

Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (Text with EEA relevance)

REGULATION (EU) 2016/426 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2016

on appliances burning gaseous fuels and repealing Directive 2009/142/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(2)</sup>,

Whereas:

- (1) Directive 2009/142/EC of the European Parliament and of the Council<sup>(3)</sup> lays down rules for the placing on the market and the putting into service of appliances burning gaseous fuels ('appliances').
- (2) Directive 2009/142/EC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards<sup>(4)</sup>. Thus, it sets out only the essential requirements applying to appliances, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>(5)</sup>. Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 2009/142/EC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.
- (3) Experience acquired from the implementation of Directive 2009/142/EC has shown the need to modify some of its provisions in order to clarify and update them and thus ensure legal certainty as regards the definitions relating to its scope, the content of the Member States' communications of the types of gas and corresponding supply pressures used on their territory and certain essential requirements.

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- (4) Since the scope, essential requirements and conformity assessment procedures have to be identical in all Member States, there is almost no flexibility in transposing a directive based on the new approach principles into national law. In order to simplify the regulatory framework, Directive 2009/142/EC should be replaced by a regulation, which is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States and thus ensures uniform implementation throughout the Union.
- (5) Decision No 768/2008/EC of the European Parliament and of the Council<sup>(6)</sup> lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. In order to ensure consistency with other sectoral product legislation, Directive 2009/142/EC should be adapted to that Decision.
- (6) Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>(7)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (7) The scope of this Regulation should reflect the scope of Directive 2009/142/EC. This Regulation should apply to domestic and non-domestic appliances intended for a number of specified applications and to fittings designed to be incorporated into such appliances.
- (8) This Regulation covers appliances and fittings which are new to the Union market when they are placed on the market; that is to say, they are either new appliances and fittings made by a manufacturer established in the Union or appliances and fittings, whether new or second-hand, imported from a third country.
- (9) Appliances possessing a historic or artistic value within the meaning of Article 36 of the Treaty on the Functioning of the European Union (TFEU) and not put into service, such as antique and other appliances serving exhibition or collection purposes, should not be considered as appliances covered by this Regulation.
- (10) This Regulation should apply to all forms of supply, including distance selling.
- (11) This Regulation should aim to ensure the functioning of the internal market of appliances and of fittings as regards gas safety risks and energy efficiency.
- (12) This Regulation should not apply in respect of aspects covered more specifically by other Union harmonisation legislation. This includes the measures adopted pursuant to Directive 2009/125/EC of the European Parliament and of the Council<sup>(8)</sup>.
- (13) This Regulation should prevent Member States from imposing stricter requirements on health, safety and energy conservation which would prohibit, restrict or impede the making available on the market and the putting into service of appliances which comply with this Regulation. However, this should not affect the possibility for Member States, when implementing other Union acts, to impose requirements which affect the energy efficiency of products, including appliances, as long as such measures are compatible with the TFEU.

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- (14) Directive 2009/28/EC of the European Parliament and of the Council<sup>(9)</sup> requires Member States to introduce in their building regulations and codes appropriate measures in order to increase the share of all kinds of energy from renewable sources in the building sector. Directive 2010/31/EU of the European Parliament and of the Council<sup>(10)</sup> requires Member States to set minimum energy performance requirements for buildings and building elements and system requirements in respect of the overall energy performance of the technical building systems which are installed in existing buildings. Directive 2012/27/EU of the European Parliament and of the Council<sup>(11)</sup> requires Member States to take sufficient measures to progressively reduce energy consumption in different areas, including in buildings.
- (15) This Regulation should not affect the obligation for Member States to adopt measures with respect to the promotion of the use of energy from renewable sources and to the energy efficiency of buildings, in accordance with Directives 2009/28/EC, 2010/31/EU and 2012/27/EU. It is consistent with the objectives of those Directives that national measures may in certain circumstances limit the installation of appliances which comply with the rational use of energy requirement of this Regulation, provided that such measures do not constitute an unjustifiable market barrier.
- (16) Member States should take the necessary steps to ensure that appliances are made available on the market and put into service only where they do not compromise the health and safety of persons, domestic animals or property, when normally used.
- (17) This Regulation should not affect the Member States' entitlement to lay down rules concerning commissioning or periodic inspections of appliances or other measures such as installer training or certification, in order to ensure the correct installation, use and maintenance of appliances, including precautionary safety measures. Those rules and measures are essential in preventing gas poisoning, including from carbon monoxide (CO), and the leakage of any substances harmful to health and safety.
- (18) This Regulation should not affect the Member States' entitlement to lay down requirements as they may deem necessary concerning installation aspects, space ventilation conditions and aspects relating to the safety of the building itself and its energy performance, provided that those requirements do not impose design requirements on appliances.
- (19) As this Regulation does not cover risks caused by appliances in the case of incorrect installation, maintenance or use, Member States should be encouraged to take measures to ensure that the public is made aware of the health and safety risks related to combustion products and the need for proper precautionary safety measures, inter alia in relation to emissions of carbon monoxide.
- (20) Although this Regulation does not regulate the gas supply conditions in the Member States, it should take into account the fact that different conditions as regards types of gas and supply pressures are in force in the Member States in the absence of harmonisation of the technical characteristics of the gaseous fuel. The composition and specifications of the types of gas and the supply pressures at the place where an appliance is put into service is very important for its safe and correct functioning,

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therefore that aspect should be taken into consideration at the design phase of the appliance in order to ensure its compatibility with the gas type(s) and supply pressure(s) it is intended for.

- (21) In order to avoid barriers to trade with regard to appliances on grounds relating to the fact that the gas supply conditions are not yet harmonised and to ensure that economic operators are sufficiently informed, Member States should communicate to the other Member States and to the Commission the types of gas and corresponding supply pressures used on their territory and any changes thereof in good time.
- (22) The communication of the gas types and supply pressures by Member States should contain the necessary information for economic operators. In that framework, the primary source of the gaseous fuel supplied is not relevant for the characteristics, the performance and the compatibility of appliances with the communicated gas supply conditions.
- (23) When determining the gas families and gas groups used on their territory, Member States are encouraged to take into account the ongoing standardisation work concerning gas qualities and thus ensure, across the Union, a coherent and coordinated approach towards harmonisation of gaseous fuels via standardisation.
- (24) When, in accordance with Directive 2009/73/EC of the European Parliament and of the Council<sup>(12)</sup> and the ongoing standardisation work of CEN on gas quality specifications, Member States take concrete measures for a wider use of biogas by injecting such gas into the gas distribution network or by distributing such gas through isolated systems, they should ensure that they update in a timely manner their communication of the types of gas in the event that the quality of the supplied gas does not remain within the already communicated quality range.
- (25) When Member States establish their national action plans in accordance with Directive 2009/28/EC in order to comply with their obligation to increase the percentage of renewable energies and in particular biogas in the total energy consumption, they are encouraged to consider the possibilities of injecting such gases into the gas distribution network.
- (26) Member States should take the necessary measures to ensure that the gas supply conditions do not constitute barriers to trade and that they do not restrict the putting into service of appliances that are compatible with the local gas supply conditions.
- (27) Appliances covered by this Regulation and complying with it should benefit from the principle of free movement of goods. Such appliances should be allowed to be put into service provided that they are compatible with the local gas supply conditions.
- (28) The appliance category marking indicated on the appliance or its data plate establishes a direct link with the gas families and/or gas groups for which an appliance has been designed to burn safely at the desired performance level and thus ensures the compatibility of the appliance with the local gas supply conditions.
- (29) The essential requirements laid down in this Regulation should be observed in order to ensure that appliances are safe when normally used at the desired performance level.

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- (30) The essential requirements should be interpreted and applied so as to take account of the state of the art at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection and rational use of energy.
- (31) Economic operators should be responsible for the compliance of appliances and of fittings with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons and domestic animals, protection of consumers and of property, and rational use of energy, and to guarantee fair competition on the Union market.
- (32) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market appliances or fittings which are in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (33) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (34) The manufacturer should provide sufficient and detailed information on the intended use of the appliance so as to allow its correct and safe installation and putting into service, use and maintenance. Such information may need to include the technical specifications of the interface between the appliance and its installation environment.
- (35) This Regulation should not apply to any natural person who manufactures an appliance on a non-professional basis and uses it exclusively for his own purposes.
- (36) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (37) It is necessary to ensure that appliances and fittings from third countries entering the Union market comply with the requirements of this Regulation, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those appliances and fittings. Provision should therefore be made for importers to make sure that the appliances and fittings they place on the market comply with the requirements of this Regulation and that they do not place on the market appliances and fittings which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that the CE marking on appliances and fittings and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (38) The distributor makes an appliance or a fitting available on the market after it has been placed on the market by the manufacturer or the importer and should act with due

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care to ensure that its handling of the appliance or fitting does not adversely affect its compliance.

- (39) When placing an appliance or a fitting on the market, every importer should indicate on the appliance or fitting his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the appliance or fitting does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the appliance or fitting.
- (40) Any economic operator that either places an appliance or a fitting on the market under his own name or trademark or modifies an appliance or a fitting in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (41) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the appliance or fitting concerned.
- (42) Ensuring traceability of an appliance or a fitting throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant appliances or fittings available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with an appliance or a fitting or to whom they have supplied an appliance or a fitting.
- (43) This Regulation should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for appliances and fittings which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture, operation, testing, the rational use of energy and installation of appliances.
- (44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (45) In order to enable economic operators to demonstrate and the competent authorities to ensure that appliances and fittings made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence

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and to avoid ad hoc variants, conformity assessment procedures should be chosen from among those modules.

- (46) Manufacturers should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of an appliance or a fitting with the requirements of this Regulation and of other relevant Union harmonisation legislation.
- (47) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for an appliance or a fitting should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (48) The CE marking, indicating the conformity of an appliance or a fitting, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship with other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on appliances and fittings should be laid down in this Regulation. Exceptions should be provided for in cases where the size or nature of the appliance or fitting does not allow the CE marking to be affixed to it.
- (49) Fittings are not appliances but intermediate products intended for appliance manufacturers and designed to be incorporated into an appliance. However, fittings should satisfy the essential requirements so as to fulfil correctly their intended purpose when incorporated into an appliance or assembled to constitute an appliance. With a view to simplification and in order to avoid any confusion and misunderstanding for manufacturers in meeting their obligations, it is considered justified that fittings should also bear the CE marking.
- (50) A check on compliance of appliances and of fittings with the essential requirements is necessary in order to provide effective protection of the health and safety of persons, of domestic animals and of property.
- (51) In order to ensure compliance of appliances and fittings with the essential requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Those procedures should be set from the conformity assessment modules laid down in Decision No 768/2008/EC.
- (52) The conformity assessment procedures set out in this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (53) Experience has shown that the criteria set out in Directive 2009/142/EC, that conformity assessment bodies have to fulfil to be notified to the Commission, are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

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- (54) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (55) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (56) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (57) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (58) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the appliances and the fittings to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.
- (59) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (60) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (61) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.



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- (62) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.
- (63) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to appliances and fittings covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (64) Directive 2009/142/EC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of an appliance or fitting. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (65) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to appliances and fittings presenting a risk to the health or safety of persons or to domestic animals or property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such appliances and fittings.
- (66) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (67) The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the content of the Member States' communications on the gas supply conditions on their territory. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (68) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>(13)</sup>.
- (69) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (70) The examination procedure should be used for the adoption of implementing acts to define the form for the Member States' communications on the gas supply conditions on their territory.

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- (71) The examination procedure should also be used for the adoption of implementing acts with respect to compliant appliances and fittings which present a risk to the health or safety of persons or to domestic animals or property.
- (72) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant appliances or fittings which present a risk to the health or safety of persons, imperative grounds of urgency so require.
- (73) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (74) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should, in line with existing practice, receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (75) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant appliances or fittings are justified or not.
- (76) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and the putting into service without the need to comply with further product requirements, of appliances and fittings that have already been placed on the market in accordance with Directive 2009/142/EC before the date of application of this Regulation. Distributors should therefore be able to supply appliances and fittings that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of this Regulation.
- (77) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (78) Since the objective of this Regulation, namely to ensure that appliances and fittings on the Union market fulfil the requirements providing for a high level of protection of health and safety of persons, of domestic animals and of property and for rational use of energy, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (79) Directive 2009/142/EC should therefore be repealed,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

## GENERAL PROVISIONS

*Article 1***Scope**

- 1 This Regulation applies to appliances and fittings.
- 2 For the purposes of this Regulation, an appliance is considered to be ‘normally used’ where the following conditions are met:
- a it is correctly installed and regularly serviced in accordance with the manufacturer's instructions;
  - b it is used with a normal variation in the gas quality and a normal fluctuation in the supply pressure as set out by [<sup>F1</sup>the Secretary of State under] Article 4(1);
  - c it is used in accordance with its intended purpose or in a way which can be reasonably foreseen.
- 3 This Regulation does not apply to appliances specifically designed:
- a for use in industrial processes carried out on industrial premises;
  - b for use on aircrafts and railways;
  - c for research purposes for temporary use in laboratories.

For the purposes of this paragraph, an appliance is considered to be ‘specifically designed’ when the design is only intended to address a specific need for a specific process or use.

- 4 Where, for appliances or fittings, the aspects covered by this Regulation are covered more specifically by other [<sup>F2</sup>enactments], this Regulation does not apply or ceases to apply to such appliances or fittings in respect of those aspects.

- 5 The rational use of energy essential requirement laid down in point 3.5 of Annex I to this Regulation does not apply to appliances covered by [<sup>F3</sup>an implementing measure within the meaning given in the Ecodesign for Energy-Related Products Regulations 2010].

<sup>F4</sup>6 .....

**Textual Amendments**

- F1** Words in Art. 1(2)(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(2)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Art. 1(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(2)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 1(5) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(2)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Art. 1(6) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(2)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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## Article 2

### Definitions

For the purposes of this Regulation the following definitions apply:

- (1) ‘appliances’ means appliances burning gaseous fuels used for cooking, refrigeration, air-conditioning, space heating, hot water production, lighting or washing, and also forced draught burners and heating bodies to be equipped with such burners;
- (2) ‘fittings’ means safety devices, controlling devices or regulating devices and sub-assemblies thereof, designed to be incorporated into an appliance or to be assembled to constitute an appliance;
- (3) ‘burning’ means a process in which gaseous fuel reacts with oxygen producing heat or light;
- (4) ‘washing’ means the entire washing process, including drying and ironing;
- (5) ‘cooking’ means the art or practice of preparing or warming food for consumption with the use of heat and employing a wide range of methods;
- (6) ‘gaseous fuel’ means any fuel which is in a gaseous state at a temperature of 15 °C under an absolute pressure of 1 bar;
- (7) ‘industrial process’ means the extraction, growth, refining, processing, production, manufacture or preparation of materials, plants, livestock, animal products, food or other products with a view to their commercial use;
- (8) ‘industrial premises’ means any place where the main activity carried out is an industrial process that would be subject to specific national health and safety regulations;
- (9) ‘gas family’ means a group of gaseous fuels with similar burning behaviour linked together by a range of Wobbe indices;
- (10) ‘gas group’ means a specified range of Wobbe indices within that of the gas family concerned;
- (11) ‘Wobbe index’ means an indicator of the interchangeability of fuel gases used to compare the combustion energy output of different composition fuel gases in an appliance;
- (12) ‘appliance category’ means the identification of gas families and/or gas groups that an appliance is designed to burn safely and at the desired performance level, as indicated by the appliance category marking;
- (13) ‘energy efficiency’ means the ratio of output of performance of an appliance to input of energy;
- (14) ‘making available on the market’ means any supply of an appliance or a fitting for distribution or use on the [F5market of Great Britain] in the course of a commercial activity, whether in return for payment or free of charge;
- (15) ‘placing on the market’ means the first making available of an appliance or a fitting on the [F6market of Great Britain];

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- (16) ‘putting into service’ means the first use of an appliance in [<sup>F7</sup>Great Britain] by its end-user;
- (17) ‘manufacturer’ means any natural or legal person who manufactures an appliance or a fitting or who has an appliance or a fitting designed or manufactured, and markets that appliance or fitting under his name or trademark or uses the appliance for his own purposes;
- (18) ‘authorised representative’ means any natural or legal person established within the [<sup>F8</sup>United Kingdom] who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (19) [<sup>F9</sup> “importer” means a person who—
- a is established in the United Kingdom and places an appliance or fitting from a country outside of the United Kingdom on the market; or
  - b is established in Northern Ireland and places an appliance or fitting on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;]
- (20) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an appliance or a fitting available on the market;
- (21) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;
- (22) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by an appliance or a fitting;
- (23) <sup>F10</sup> .....
- (24) <sup>F10</sup> .....
- (25) <sup>F10</sup> .....
- (26) ‘conformity assessment’ means the process demonstrating whether the essential requirements of this Regulation relating to an appliance or a fitting have been fulfilled;
- (27) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (28) ‘recall’ means any measure aimed at achieving the return of an appliance that has already been made available to the end-user or of a fitting that has already been made available to an appliance manufacturer;
- (29) ‘withdrawal’ means any measure aimed at preventing an appliance or a fitting in the supply chain from being made available on the market;
- (30) <sup>F11</sup> .....
- (31) <sup>F11</sup> .....
- (32) [<sup>F12</sup> ‘approved body’ has the meaning given in Article 19;
- (33) ‘designated standard’ has the meaning given in Article 6A;

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- (34) ‘enforcement authority’ means a person enforcing this Regulation under regulation 4 of the Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018 (S.I. 2018/389);
- (35) ‘UK marking’ means the marking in the form set out in Annex 2 of Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93;
- (36) ‘UK national accreditation body’ means the body appointed by the Secretary of State in accordance with Article 4 of Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93;
- (37) ‘Regulation 2016/426 (pre-exit)’ means Regulation (EU) 2016/426 of the European Parliament and of the Council on appliances burning gaseous fuels and repealing Directive 2009/142/EC, as it had effect immediately before IP completion day;
- (38) In this Regulation, references to “the market surveillance authority” are to be construed in accordance with regulation 3 of the Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018.]

#### Textual Amendments

- F5** Words in Art. 2(14) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(4)); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 2(15) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(4)); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 2(16) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(5)); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 2(18) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 5 para. 1(6)(b)**
- F9** Art. 2(19) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(3)); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 2(23)-(25) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Art. 2(30)-(31) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 2(32)-(38) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(3)(e)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(v)(iii)); 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

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### Article 3

#### Making available on the market and putting into service

1 Appliances shall only be made available on the market and put into service if, when normally used, they comply with this Regulation.

2 Fittings shall only be made available on the market if they comply with this Regulation.

<sup>F13</sup> .....

#### Textual Amendments

**F13** Art. 3(3) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(4)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F14</sup> Article 4

#### Gas supply conditions

1 The Secretary of State must publish information, in accordance with Annex II, about the types of gas and corresponding supply pressures of gaseous fuels used in the United Kingdom.

2 The information that is published under paragraph 1, may be—

- a published in such form and manner as the Secretary of State considers appropriate;
- b reviewed by the Secretary of State at any time, and if it is revised following such a review, the Secretary of State must publish revised information as soon as reasonably practicable following that review.

3 Where the Secretary of State considers it necessary to do so to take account of any technical developments with regard to gas supply conditions, the Secretary of State may by regulations amend the content of the information regarding gas supply conditions as set out in Annex II.

4 Before making regulations under this Article, the Secretary of State must consult such persons as the Secretary of State considers appropriate.

5 Where regulations are made under this Article, the Secretary of State must, as soon as reasonably practicable after those regulations come into force, publish revised information in accordance with Annex II as amended by those regulations.

6 Regulations made under this Article may—

- a make different provisions for different cases; and
- b make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

7 Regulations made under this Article are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.]

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

### Textual Amendments

- F14** Art. 4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(5)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 5

### Essential requirements

Appliances and fittings shall meet the essential requirements set out in Annex I which apply to them.

## Article 6

### <sup>F15</sup>**Making available, putting into service and exhibition at trade fairs, etc]**

1 <sup>F16</sup>Nothing in this Regulation prohibits, restricts or impedes], on grounds relating to the aspects covered by this Regulation, <sup>F17</sup>... the making available on the market and the putting into service of appliances which comply with this Regulation.

2 <sup>F18</sup>Nothing in this Regulation prohibits, restricts or impedes], on grounds relating to the risks covered by this Regulation, <sup>F19</sup>... the making available on the market of fittings which comply with this Regulation.

3 At trade fairs, exhibitions, demonstrations or similar events, <sup>F20</sup>nothing in this Regulation prevents] the showing of appliances or fittings which do not comply with this Regulation, provided that a visible sign clearly indicates that such appliances or fittings do not comply with this Regulation and that they are not for sale until they have been brought into conformity. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons, domestic animals and property.

### Textual Amendments

- F15** Art. 6 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 6(1) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(b)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 6(1) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 6(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(b)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 6(2) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



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**F20** Words in Art. 6(3) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(6)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F21</sup>Article 6A

### Designated standard

1 Subject to paragraphs 6 and 7, in this Regulation a “designated standard” means a technical specification which is—

- a adopted by a recognised standardisation body [<sup>F22</sup>or an international standardising body], for repeated or continuous application, with which compliance is not compulsory; and
- b designated by the Secretary of State, by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

2 For the purposes of paragraph 1, “technical specification” means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

- a the characteristics required of a product, including—
  - i levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
  - ii the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
- b production methods and processes relating to the product, where these have an effect on the characteristics of the product.

3 For the purposes of this Article, a “recognised standardisation body” means any one of the following organisations—

- a the European Committee for Standardisation (CEN);
- b the European Committee for Electrotechnical Standardisation (Cenelec);
- c the European Telecommunications Standards Institute (ETSI);
- d the British Standards Institution (BSI).

3A. [<sup>F23</sup>In this Article “international standardising body” has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]

4 When considering whether the manner of publication of a reference is appropriate in accordance with paragraph 1(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

5 Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with [<sup>F24</sup>such] technical specifications adopted by the other recognised standardisation bodies [<sup>F25</sup>or by international standardising bodies as the Secretary of State considers to be relevant].

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

6 The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph 1(b).

7 Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

8 In this Article, a reference to a “product” is a reference to an appliance or fitting to which this Regulation applies.

9 The Secretary of State may, by regulations, amend paragraph 3 to reflect any changes in the name or structure of the recognised standardisation bodies.

10 Regulations made under paragraph 9 must be made by statutory instrument, subject to annulment in pursuance of a resolution of either House of Parliament.]

#### Textual Amendments

- F21** Art. 6A inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(7)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 6A(1)(a) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 24(a)**; S.I. 2020/1662, reg. 2(ee)
- F23** Art. 6A(3A) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 24(b)**; S.I. 2020/1662, reg. 2(ee)
- F24** Word in Art. 6A(5) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 24(c)(i)**; S.I. 2020/1662, reg. 2(ee)
- F25** Words in Art. 6A(5) inserted (31.12.2020) by [European Union \(Future Relationship\) Act 2020 \(c. 29\)](#), s. 40(7), **Sch. 4 para. 24(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

## CHAPTER II

### OBLIGATIONS OF ECONOMIC OPERATORS

#### Article 7

#### Obligations of manufacturers

1 When placing their appliances or fittings on the market or when using the appliances for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2 Manufacturers shall draw up the technical documentation referred to in Annex III (‘technical documentation’) and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of an appliance or a fitting with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up [<sup>F26</sup>a] declaration of conformity and affix the [<sup>F27</sup>UK] marking.

3 Manufacturers shall keep the technical documentation and the <sup>F28</sup>... declaration of conformity for 10 years after the appliance or the fitting has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in appliance or fitting design or characteristics and changes in the [F<sup>29</sup>designated] standards or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an appliance, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of appliances made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming appliances and fittings and recalls of such appliances and fittings, and shall keep distributors informed of any such monitoring.

5 Manufacturers shall ensure that their appliances and fittings bear a type, batch or serial number or other element allowing their identification, and the inscriptions provided for in Annex IV.

Where the size or nature of the appliance or the fitting does not allow it, manufacturers shall ensure that the required information is provided on the packaging or in a document accompanying the appliance or the fitting.

6 Manufacturers shall indicate on the appliance their name, registered trade name or registered trade mark, and the postal address at which they can be contacted or, where that is not possible, on the packaging or in a document accompanying the appliance. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by consumers and other end-users and the [F<sup>30</sup>market surveillance authority].

Manufacturers shall indicate on the fitting their name, registered trade name or registered trade mark, and the postal address at which they can be contacted or, where that is not possible, on the packaging or in a document accompanying the fitting. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by appliance manufacturers and the [F<sup>30</sup>market surveillance authority].

7 Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, [F<sup>31</sup>that are clear, legible and in easily understandable English].

Manufacturers shall ensure that the fitting is accompanied by a copy of the F<sup>32</sup>... declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, [F<sup>31</sup>that are clear, legible and in easily understandable English].

However, where a large number of fittings are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy of the F<sup>32</sup>... declaration of conformity.

8 Manufacturers who consider or have reason to believe that an appliance or a fitting which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that appliance or fitting into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the appliance or the fitting presents a risk, manufacturers shall immediately inform the [F<sup>33</sup>enforcement authority] to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

9 Manufacturers shall, further to a reasoned request from [<sup>F34</sup>the enforcement authority], provide it with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting with this Regulation, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by appliances or fittings which they have placed on the market.

#### Textual Amendments

- F26** Word in Art. 7(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(a)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Word in Art. 7(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Word in Art. 7(3) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Word in Art. 7(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 7(6) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in Art. 7(7) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(e)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F32** Word in Art. 7(7) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(e)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F33** Words in Art. 7(8) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(f)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 7(9) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(8)(g)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Article 8

#### Authorised representatives

1 A manufacturer may, by a written mandate, appoint [<sup>F35</sup>a person established in the United Kingdom as their]<sup>F36</sup>... authorised representative.

The obligations laid down in Article 7(1) and the obligation to draw up technical documentation shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

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- a keep the <sup>F37</sup>... declaration of conformity and the technical documentation at the disposal of [<sup>F38</sup>the market surveillance authority] for 10 years after the appliance or the fitting has been placed on the market;
- b further to a reasoned request from [<sup>F39</sup>the enforcement authority], provide that authority with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting;
- c cooperate with the [<sup>F40</sup>enforcement authority], at their request, on any action taken to eliminate the risks posed by appliances or fittings covered by the authorised representative's mandate.

#### Textual Amendments

- F35** Words in Art. 8(1) inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F36** Word in Art. 8(1) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F37** Word in Art. 8(2)(a) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(b\)\(i\)\(aa\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F38** Words in Art. 8(2)(a) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(b\)\(i\)\(bb\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F39** Words in Art. 8(2)(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(b\)\(ii\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in Art. 8(2)(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(9\)\(b\)\(iii\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Article 9

#### Obligations of importers

- 1 Importers shall place only compliant appliances or fittings on the market.
- 2 Before placing an appliance on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the appliance bears the [<sup>F41</sup>UK] marking and is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

Before placing a fitting on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the [<sup>F41</sup>UK] marking and is accompanied by a copy of the <sup>F42</sup>... declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

Where an importer considers or has reason to believe that an appliance or a fitting is not in conformity with the essential requirements set out in Annex I, he shall not place the appliance or the fitting on the market until it has been brought into conformity. Furthermore, where the appliance or the fitting presents a risk, the importer shall inform the manufacturer and the market surveillance [<sup>F43</sup>authority] to that effect.

3 Importers shall indicate on the appliance their name, registered trade name or registered trade mark, and the postal address at which they can be contacted <sup>F44</sup>.... The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance [<sup>F45</sup>authority].

Importers shall indicate on the fitting their name, registered trade name or registered trade mark, and the postal address at which they can be contacted <sup>F44</sup>... The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance [<sup>F45</sup>authority].

[<sup>F46</sup>The obligation set out in the first and second subparagraphs of this paragraph 3 to indicate information on the appliance or fitting does not apply where—

a either—

i it is not possible to indicate that information on the appliance or fitting, or

ii the importer has imported the appliance or fitting from an EEA state or Switzerland and places it on the market within the period of [<sup>F47</sup>seven years] beginning with IP completion day, and

b before placing the appliance or fitting on the market, the importer sets out the information referred to in the first and second subparagraphs on the packaging of the appliance or fitting or in a document accompanying the appliance or fitting.]

4 Importers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, [<sup>F48</sup>that are clear, legible and in easily understandable English].

Importers shall ensure that the fitting is accompanied by a copy of the <sup>F49</sup>... declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, [<sup>F48</sup>that are clear, legible and in easily understandable English].

5 Importers shall ensure that, while an appliance or a fitting is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6 When deemed appropriate with regard to the risks presented by an appliance, importers shall, to protect the health and safety of consumers and other users, carry out sample testing of appliances made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming appliances and fittings and recalls of such appliances and fittings, and shall keep distributors informed of any such monitoring.

7 Importers who consider or have reason to believe that an appliance or a fitting which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that appliance or fitting into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the appliance or the fitting presents a risk, importers shall immediately inform the [<sup>F50</sup>enforcement authority] to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 Importers shall, for 10 years after the appliance or the fitting has been placed on the market, keep a copy of the <sup>F51</sup>... declaration of conformity at the disposal of the market

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

surveillance [<sup>F52</sup>authority] and ensure that the technical documentation can be made available to [<sup>F53</sup>that authority], upon request.

9 Importers shall, further to a reasoned request from [<sup>F54</sup>the enforcement authority], provide it with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by appliances or fittings which they have placed on the market.

#### Textual Amendments

- F41** Word in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(a)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F42** Word in Art. 9(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F43** Word in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(a)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F44** Words in Art. 9(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(b)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F45** Word in Art. 9(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(b)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Art. 9(3) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(b)(ii)** (as amended by S.I. 2019/1246, regs. 1(3), 5; S.I. 2020/676, regs. 1(1), 2; S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(v)(iv); and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 2(1)(o)); 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in Art. 9(3)(a)(ii) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3**
- F48** Words in Art. 9(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(c)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F49** Word in Art. 9(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(c)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F50** Words in Art. 9(7) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F51** Word in Art. 9(8) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(e)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F52** Word in Art. 9(8) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(e)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in Art. 9(8) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(10)(e)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

**F54** Words in Art. 9(9) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(10)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 10

### Obligations of distributors

1 When making an appliance or a fitting available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2 Before making an appliance available on the market, distributors shall verify that the appliance bears the [<sup>F55</sup>UK] marking and that it is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, [<sup>F56</sup>that are clear, legible and in easily understandable English], and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Before making a fitting available on the market, distributors shall verify that the fitting bears the [<sup>F57</sup>UK] marking and that it is accompanied by a copy of the [<sup>F58</sup>... declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, [<sup>F59</sup>that are clear, legible and in easily understandable English], and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Where a distributor considers or has reason to believe that an appliance or a fitting is not in conformity with the essential requirements set out in Annex I, he shall not make the appliance or the fitting available on the market until it has been brought into conformity. Furthermore, where the appliance or the fitting presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance [<sup>F60</sup>authority].

3 Distributors shall ensure that, while an appliance or a fitting is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4 Distributors who consider or have reason to believe that an appliance or a fitting which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that appliance or fitting into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the appliance or the fitting presents a risk, distributors shall immediately inform the [<sup>F61</sup>enforcement authority] to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from [<sup>F62</sup>the enforcement authority], provide it with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by appliances or fittings which they have made available on the market.



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

### Textual Amendments

- F55** Word in Art. 10(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F56** Words in Art. 10(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F57** Word in Art. 10(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(ii)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F58** Word in Art. 10(2) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(ii)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Art. 10(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(ii)(cc)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F60** Word in Art. 10(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(a)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F61** Words in Art. 10(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F62** Words in Art. 10(5) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(11)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 11

### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer under Article 7, where he places an appliance or a fitting on the market under his name or trademark or modifies an appliance or a fitting already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

## Article 12

### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance [<sup>F63</sup>authority]:

- (a) any economic operator who has supplied them with an appliance or a fitting;
- (b) any economic operator to whom they have supplied an appliance or a fitting.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the appliance or the fitting and for 10 years after they have supplied the appliance or the fitting.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F63** Word in Art. 12 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(12)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER III

### CONFORMITY OF APPLIANCES AND FITTINGS

#### <sup>F64</sup> Article 13

#### Presumption of conformity of appliances and fittings

1 Appliances and fittings which are in conformity with a designated standard or part thereof shall be presumed to be in conformity with the essential requirements set out in Annex I covered by that standard or part thereof.

2 The presumption in paragraph 1 is rebuttable.]

#### Textual Amendments

**F64** Art. 13 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(13)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 14

#### Conformity assessment procedures for appliances and fittings

1 Before an appliance or a fitting is placed on the market, the manufacturer shall submit it to a conformity assessment procedure in accordance with paragraph 2 or 3.

2 The conformity of series-manufactured appliances and fittings with the requirements of this Regulation shall be assessed by means of the <sup>F65</sup>... type-examination (Module B — production type) set out in point 1 of Annex III, combined with one of the following modules, at the choice of the manufacturer:

- a conformity to type based on internal production control plus supervised product checks at random intervals (Module C2), set out in point 2 of Annex III;
- b conformity to type based on quality assurance of the production process (Module D), set out in point 3 of Annex III;
- c conformity to type based on product quality assurance (Module E), set out in point 4 of Annex III;
- d conformity to type based on product verification (Module F), set out in point 5 of Annex III.

3 In the case of an appliance or a fitting produced as a single unit or in small quantities, the manufacturer may choose one of the procedures set out in paragraph 2 of this Article or conformity based on unit verification (Module G) set out in point 6 of Annex III.

*Status:* Point in time view as at 31/12/2022.

*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)

4 Records and correspondence relating to conformity assessment of an appliance or a fitting shall be drawn up in [<sup>F66</sup>English] or in a language accepted by [<sup>F67</sup>the approved body].

#### Textual Amendments

- F65** Word in Art. 14(2) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(14)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F66** Word in Art. 14(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(14)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F67** Words in Art. 14(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(14)(b)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Article 15

#### <sup>F68</sup>... Declaration of conformity

1 The <sup>F69</sup>... declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2 The <sup>F70</sup>... declaration of conformity shall have the model structure set out in Annex V, shall contain the elements specified in the relevant modules set out in Annex III and shall be continuously updated. It shall be [<sup>F71</sup>prepared in or translated into English].

3 In order to assist compliance of finished appliances with the applicable essential requirements set out in Annex I, the <sup>F72</sup>... declaration of conformity for a fitting shall state the characteristics of the fitting and shall contain instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance. The <sup>F72</sup>... declaration of conformity shall be in [<sup>F73</sup>English].

[<sup>F74</sup> Where an appliance or a fitting is subject to more than one enactment requiring a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.]

5 By drawing up the <sup>F75</sup>... declaration of conformity, the manufacturer shall assume responsibility for the compliance of the appliance or the fitting with the requirements laid down in this Regulation.

6 A copy of the <sup>F76</sup>... declaration of conformity shall be supplied with the fitting.

#### Textual Amendments

- F68** Word in Art. 15 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(15)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F69** Word in Art. 15(1) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(15)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F70** Word in Art. 15(2) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(15)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- F71** Words in Art. 15(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F72** Word in Art. 15(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(c)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F73** Word in Art. 15(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(c)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F74** Art. 15(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F75** Word in Art. 15(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F76** Word in Art. 15(6) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(15)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 16

### General principles of the [F77UK] marking

The [F78UK] marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### Textual Amendments

- F77** Word in Art. 16 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(16)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F78** Word in Art. 16 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(16)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 17

### Rules and conditions for affixing the [F79UK] marking

[F80A1 Paragraph 1 is subject to paragraph (1A).]

1 The [F81UK] marking shall be affixed visibly, legibly and indelibly to the appliance and the fitting or to their data plate as far as relevant. Where that is not possible or not warranted on account of the nature of the appliance or the fitting, it shall be affixed to the packaging and to the documents accompanying the appliance or the fitting.

[F821A For a period of [F83seven years] beginning with IP completion day, paragraph 1 does not apply where the UK marking is affixed visibly, legibly and indelibly to—

- a a label affixed to the appliance and fitting or their data plate; or
- b a document accompanying the appliance and fitting or their data plate.]

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2 The [F84UK] marking shall be affixed before the appliance or the fitting is placed on the market.

3 The [F85UK] marking shall be followed by the identification number of the [F86approved] body involved in the production control phase of the appliance or of the fitting and by the last two digits of the year in which the [F85UK] marking was affixed. The identification number of the [F86approved] body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4 The [F87UK] marking and the identification number referred to in paragraph 3 may be followed by any other mark indicating a special risk or use.

F885 .....

#### Textual Amendments

- F79** Word in Art. 17 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F80** Art. 17(A1) inserted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(6)); 2020 c. 1, Sch. 5 para. 1(1)
- F81** Word in Art. 17(1) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F82** Art. 17(1A) inserted by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(ab)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(6)); 2020 c. 1, Sch. 5 para. 1(1)
- F83** Words in Art. 17(1A) substituted (E.W.S.) (31.12.2022) by virtue of [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022 \(S.I. 2022/1393\)](#), regs. 1(1), **3, Sch. 2**
- F84** Word in Art. 17(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F85** Word in Art. 17(3) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(b)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F86** Word in Art. 17(3) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F87** Word in Art. 17(4) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F88** Art. 17(5) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(17)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 18

#### Inscriptions

1 The inscriptions referred to in Annex IV shall be affixed visibly, legibly and indelibly to the appliance or to its data plate and, as far as relevant, to the fitting or to its data plate.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

2 The inscriptions referred to in Annex IV shall be affixed before the appliance or the fitting is placed on the market.

## CHAPTER IV

### [<sup>F89</sup> APPROVAL OF CONFORMITY ASSESSMENT BODIES]

#### [<sup>F90</sup> Article 19

#### Approved bodies

- 1 An approved body is a conformity assessment body which—
  - a has been approved by the Secretary of State pursuant to the procedure set out in Article 20 (approval of conformity assessment bodies); or
  - b immediately before IP completion day was a notified body in respect of which the Secretary of State had taken no action under Article 29 (changes to notifications) of Regulation 2016/426 (pre-exit), to suspend or withdraw the body's status as a notified body.
- 2 Paragraph 1 has effect subject to Article 29 (restriction, suspension or withdrawal of approval).
- 3 In this Chapter—
 

“notified body” means a body—

  - (a) which the Secretary of State had, before IP completion day, notified to the European Commission and the member States of the European Union in accordance with Article 19 of Regulation 2016/426 (pre-exit); and
  - (b) in respect of which no objections had been raised, as referred to in Article 27(5) of Regulation 2016/426 (pre-exit);

“approved body requirements” means the requirements set out in Article 23.]

#### Textual Amendments

**F90** Art. 19 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(19)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(v)(v)); 2020 c. 1, Sch. 5 para. 1(1)

#### [<sup>F91</sup> Article 20

#### Approval of conformity assessment bodies

- 1 The Secretary of State may approve only those conformity assessment bodies that qualify for approval.
- 2 A conformity assessment body qualifies for approval if the first and second conditions below are met.
- 3 The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

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- a a description of—
  - i the conformity assessment activities that the conformity assessment body intends to carry out;
  - ii the conformity assessment procedure in respect of which the conformity assessment body claims to be competent; and
  - iii the category of appliance or fitting in respect of which the conformity assessment body claims to be competent; and
- b either—
  - i an accreditation certificate; or
  - ii the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

4 The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

5 For the purposes of paragraph 4, the Secretary of State may accept an accreditation certificate provided in accordance with paragraph 3(b)(i), as sufficient evidence that the conformity assessment body meets the approved body requirements.

6 When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

- a have regard to any other matter which appears to the Secretary of State to be relevant; and
- b set conditions that the conformity assessment body must meet.

7 For the purposes of this Article, “accreditation certificate” means a certificate issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.]

#### **Textual Amendments**

**F91** Art. 20 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(20)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### *f<sup>F92</sup> Article 21*

#### **UK national accreditation body**

The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- a assessing whether a conformity assessment body meets the approved body requirements;
- b monitoring approved bodies in accordance with Article 22; and
- c compiling and maintaining the register of approved bodies, in accordance with Article 28.]

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F92** Art. 21 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(21)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### <sup>F93</sup> Article 22

#### Monitoring obligations

The Secretary of State must monitor each approved body with a view to verifying that the body—

- a continues to meet—
  - i the approved body requirements;
  - ii any conditions set by the Secretary of State under Article 20(6)(b); and
- b carries out its functions in accordance with this Regulation.]

#### Textual Amendments

**F93** Art. 22 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(22)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### Article 23

#### <sup>F94</sup> Approved Body Requirements]

1 For the purposes of [<sup>F95</sup>approval], a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established [<sup>F96</sup>in the United Kingdom] and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the appliance or the fitting it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of appliances or fittings which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4 A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the appliances or the fittings which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed appliances or fittings that are necessary for the operations of the conformity assessment body or the use of such appliances or fittings for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the



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design, manufacture or construction, the marketing, installation, use or maintenance of those appliances or fittings, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are [<sup>F97</sup>approved]. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex III and in relation to which it has been [<sup>F98</sup>approved], whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times, and for each conformity assessment procedure and each kind or category of appliances or fittings in relation to which it has been [<sup>F98</sup>approved], a conformity assessment body shall have at its disposal the necessary:

- a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- b descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as [<sup>F99</sup>an approved body] and other activities;
- c procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the appliance or fitting technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out conformity assessment tasks shall have the following:

- a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been [<sup>F100</sup>approved];
- b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- c appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable [<sup>F101</sup>designated] standards and of the relevant provisions of [<sup>F102</sup>this Regulation and any other relevant United Kingdom legislation];
- d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

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8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and of the personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9 Conformity assessment bodies shall take out liability insurance unless [<sup>F103</sup>the Secretary of State] is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex III or any provision of [<sup>F104</sup>United Kingdom] law giving effect to it, except in relation to the [<sup>F105</sup>enforcement authority]. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of [<sup>F106</sup>any approved] body coordination group established [<sup>F107</sup>by the Secretary of State] and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Textual Amendments

- F94** Art. 23 heading substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F95** Word in Art. 23(1) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F96** Words in Art. 23(2) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F97** Word in Art. 23(4) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F98** Word in Art. 23(6) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(e)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F99** Words in Art. 23(6)(b) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(e)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F100** Word in Art. 23(7)(a) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F101** Word in Art. 23(7)(c) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(f)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F102** Words in Art. 23(7)(c) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(f)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F103** Words in Art. 23(9) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(g)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- F104** Words in Art. 23(10) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(h)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F105** Words in Art. 23(10) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(h)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F106** Words in Art. 23(11) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F107** Words in Art. 23(11) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(23)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### *F108* Article 24

#### **Presumption of conformity of approved bodies**

1 Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such a standard), the Secretary of State must presume that the conformity assessment body meets the approved body requirements covered by that standard (or the part of that standard).

2 The presumption in paragraph 1 is rebuttable.]

#### **Textual Amendments**

- F108** Art. 24 substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(24)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### *F109* Article 25

#### **Subsidiaries of, and subcontracting by, approved bodies**

1 An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- a the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
- b the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- c the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

2 The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

3 Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

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- a the assessment of the qualifications of the subcontractor or the subsidiary; and
- b the conformity assessment activity carried out by the subcontractor or subsidiary.

4 In this Article, “subsidiary” has the meaning given to it by section 1159 of the Companies Act 2006.]

#### Textual Amendments

**F109** Art. 25 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(25)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### *F110* Article 26

### Application for notification

#### Textual Amendments

**F110** Art. 26 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(26)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### *F111* Article 27

### Notification procedure

#### Textual Amendments

**F111** Art. 27 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(26)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### *F112* Article 28

### Identification numbers and register of approved bodies

- 1 The Secretary of State must—
  - a assign an approved body identification number to each approved body; and
  - b compile and maintain a register of—
    - i approved bodies;
    - ii their approved body identification numbers;
    - iii the activities for which they have been approved; and
    - iv any restrictions on those activities.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

2 The register referred to in paragraph 1 must be made publicly available.]

#### Textual Amendments

**F112** Art. 28 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(27)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### *F113* Article 29

#### Restriction, suspension or withdrawal of approval

- 1 Where the Secretary of State determines that an approved body—
  - a no longer meets an approved body requirement, or
  - b is failing to fulfil its obligations under these Regulations, other than a condition referred to in Article 20(6)(b),the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under Article 20.
- 2 Where the Secretary of State determines that an approved body no longer meets a condition referred to in Article 20(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under Article 20.
- 3 In deciding what action to take under paragraph 1 or 2, the Secretary of State must have regard to the seriousness of the non-compliance.
- 4 Before taking action under paragraph 1 or 2, the Secretary of State must—
  - a give notice in writing to the approved body of the proposed action and the reasons for it;
  - b give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
  - c consider any such representations made by the approved body.
- 5 Where the Secretary of State has taken action in respect of an approved body under paragraph 1 or 2, or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—
  - a transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or
  - b keep its files relating to the activities it has undertaken as an approved body available for inspection by the Secretary of State and market surveillance authority for a period of 10 years from the date they were created.
- 6 The activities undertaken as an approved body referred to in paragraph 5 include any activities that the body has undertaken as a notified body.]

#### Textual Amendments

**F113** Art. 29 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(28)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

## <sup>F114</sup>Article 30

### Challenge of the competence of notified bodies

#### Textual Amendments

**F114** Art. 30 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(29)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 31

### Operational obligations of [<sup>F115</sup>approved] bodies

1 [<sup>F116</sup>Approved] bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.

[<sup>F117</sup>1A Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures in respect of which —

- a the body's approval was given under Article 20; or
- b the body's notification as a notified body was made.]

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the appliance or fitting technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the appliance or the fitting with this Regulation.

3 Where [<sup>F118</sup>an approved] body finds that the essential requirements set out in Annex I or corresponding [<sup>F119</sup>designated] standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

4 Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, [<sup>F120</sup>an approved] body finds that an appliance or a fitting no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision, if necessary.

5 Where corrective measures are not taken or do not have the required effect, the [<sup>F121</sup>approved] body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

- F115** Word in Art. 31 heading substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(a)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F116** Word in Art. 31(1) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(b)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F117** Art. 31(1A) inserted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(c)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F118** Words in Art. 31(3) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(d)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F119** Word in Art. 31(3) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(e)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F120** Words in Art. 31(4) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(d)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F121** Word in Art. 31(5) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(30)(a)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 32

### Appeal against decisions of <sup>F122</sup>approved] bodies

<sup>F123</sup>Approved] bodies shall ensure that an appeal procedure against their decisions is available.

#### Textual Amendments

- F122** Word in Art. 32 heading substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(31)(b)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F123** Word in Art. 32 substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696)*, reg. 1, **Sch. 36 para. 2(31)(a)** (as amended by *S.I. 2020/676*, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 33

### Information obligation on <sup>F124</sup>approved] bodies

- 1 <sup>F125</sup>Approved] bodies shall inform the <sup>F126</sup>Secretary of State] of the following:
  - a any refusal, restriction, suspension or withdrawal of a certificate or approval decision;
  - b any circumstances affecting the scope of or the conditions for <sup>F127</sup>their approval];
  - c any request for information which they have received from <sup>F128</sup>the market surveillance authority] regarding conformity assessment activities;

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- d on request, conformity assessment activities performed within the scope of their [<sup>F129</sup>approval] and any other activity performed, including cross-border activities and subcontracting.
- 2 [<sup>F130</sup>Approved] bodies shall provide [<sup>F131</sup>other approved bodies] under this Regulation carrying out similar conformity assessment activities covering the same appliances or fittings with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Textual Amendments

- F124** Word in Art. 33 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F125** Word in Art. 33(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(b)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F126** Words in Art. 33(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(b)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F127** Words in Art. 33(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(b)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F128** Words in Art. 33(1)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(b)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F129** Word in Art. 33(1)(d) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(b)(iv)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F130** Word in Art. 33(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(c)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F131** Words in Art. 33(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(32)(c)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F132</sup>Article 34

### Exchange of experience

#### Textual Amendments

- F132** Art. 34 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(33)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

### <sup>F133</sup>Article 35

#### Coordination of notified bodies

##### Textual Amendments

**F133** Art. 35 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(33)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

##### Textual Amendments

**F89** Words in Ch. 4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(18)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER V

### [<sup>F134</sup>MARKET SURVEILLANCE AND CONTROL OF APPLIANCES AND FITTINGS ENTERING THE MARKET OF GREAT BRITAIN]

#### Article 36

#### [<sup>F135</sup>Market surveillance and control of appliances and fittings entering the United Kingdom market]

[<sup>F136</sup>Articles 15(3), 16 to 22 and 26 to 29] of Regulation (EC) No 765/2008 shall apply to appliances and fittings covered by this Regulation.

##### Textual Amendments

**F135** Art. 36 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(35)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F136** Words in Art. 36 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(35)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Article 37

#### Procedure <sup>F137</sup>... for dealing with appliances or fittings presenting a risk

1 Where the market surveillance [<sup>F138</sup>authority has] sufficient reason to believe that an appliance or fitting covered by this Regulation presents a risk to the health or safety of persons or to domestic animals or property, [<sup>F139</sup>the authority] shall carry out an evaluation in relation to the

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appliance or fitting concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance [<sup>F140</sup>authority] for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance [<sup>F141</sup>authority finds] that the appliance or fitting does not comply with the requirements laid down in this Regulation, [<sup>F142</sup>the authority] shall without delay require the relevant economic operator to take all appropriate corrective action to bring the appliance or fitting into compliance with those requirements, to withdraw the appliance or fitting from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as [<sup>F142</sup>the authority] may prescribe.

The market surveillance [<sup>F143</sup>authority] shall inform the relevant [<sup>F144</sup>approved] body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

<sup>F145</sup>2 .....

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the appliances and fittings concerned that he has made available on the market  
<sup>F146</sup> .....

4 Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance [<sup>F147</sup>authority] shall take all appropriate <sup>F148</sup>... measures to prohibit or restrict the appliances or fittings being made available on [<sup>F149</sup>the market], to withdraw the appliance or fitting from that market or to recall it.

<sup>F150</sup> ...

<sup>F151</sup>5 .....

<sup>F151</sup>6 .....

<sup>F151</sup>7 .....

<sup>F151</sup>8 .....

#### Textual Amendments

**F137** Words in Art. 37 heading omitted (31.12.2020) by virtue of *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F138** Words in Art. 37(1) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F139** Words in Art. 37(1) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F140** Word in Art. 37(1) substituted (31.12.2020) by *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(i)(cc)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- F141** Words in Art. 37(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(ii)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F142** Words in Art. 37(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(ii)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F143** Word in Art. 37(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(iii)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F144** Word in Art. 37(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(b)(iii)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F145** Art. 37(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F146** Words in Art. 37(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F147** Word in Art. 37(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(e)(i)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F148** Word in Art. 37(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(e)(i)(bb)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F149** Words in Art. 37(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(e)(i)(cc)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F150** Words in Art. 37(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(e)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F151** Art. 37(5)-(8) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(36)(f)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F152</sup>Article 38

### Union safeguard procedure

#### Textual Amendments

- F152** Art. 38 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(37)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

## Article 39

### Compliant appliances or fittings which present a risk

1 Where, having carried out an evaluation under Article 37(1), [<sup>F153</sup>the enforcement authority] finds that although an appliance or fitting is in compliance with this Regulation, it presents a risk to the health or safety of persons or to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the appliance or fitting concerned, when placed on the market, no longer presents that risk, to withdraw the appliance or fitting from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2 The economic operator shall ensure that corrective action is taken in respect of all the appliances or fittings concerned that he has made available on the market <sup>F154</sup>....

<sup>F155</sup><sub>3</sub> .....

<sup>F155</sup><sub>4</sub> .....

<sup>F155</sup><sub>5</sub> .....

#### Textual Amendments

- F153** Words in Art. 39(1) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(38)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F154** Words in Art. 39(2) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(38)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F155** Art. 39(3)-(5) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(38)(c)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## Article 40

### Formal non-compliance

1 Without prejudice to Article 37, where [<sup>F156</sup>the enforcement authority] makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- a the [<sup>F157</sup>UK] marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation;
- b the [<sup>F158</sup>UK] marking has not been affixed;
- c the inscriptions referred to in Annex IV have not been affixed or have been affixed in violation of Article 18;
- d the identification number of the [<sup>F159</sup>approved] body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;
- e the <sup>F160</sup>... declaration of conformity has not been drawn up or has not been drawn up correctly;
- f a copy of the <sup>F161</sup>... declaration of conformity does not accompany the fitting;

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- g the technical documentation is either not available or not complete;
- h the information referred to in Article 7(6) or Article 9(3) is absent, false or incomplete;
- i any other administrative requirement provided for in Article 7 or Article 9 is not fulfilled.

2 Where the non-compliance referred to in paragraph 1 persists, the [F162 enforcement authority] shall take all appropriate measures to restrict or prohibit the appliance or fitting being made available on the market or ensure that it is recalled or withdrawn from the market.

#### Textual Amendments

- F156** Words in Art. 40(1) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F157** Word in Art. 40(1)(a) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F158** Word in Art. 40(1)(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F159** Word in Art. 40(1)(d) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(iii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F160** Word in Art. 40(1)(e) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(iv)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F161** Word in Art. 40(1)(f) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(a)(iv)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F162** Words in Art. 40(2) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(39)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

- F134** Ch. 5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(34)** (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(7)); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER VI

### DELEGATED ACTS AND COMMITTEE PROCEDURE

#### *F163* Article 41

#### Exercise of the delegation

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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F163** Arts. 41-43 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(40)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*F163 Article 42*

### Committee procedure

#### Textual Amendments

**F163** Arts. 41-43 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(40)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER VII

### TRANSITIONAL AND FINAL PROVISIONS

*F163 Article 43*

#### Penalties

#### Textual Amendments

**F163** Arts. 41-43 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(40)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*F164 Article 44*

#### Transitional provision in relation to EU exit

- 1 In this Article, “pre-exit period” means the period beginning with 21 April 2018 and ending immediately before IP completion day.
- 2 Subject to paragraph 3, where an appliance or fitting was made available on the market during the pre-exit period, despite the amendments made by Schedule 36 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation to which a person was subject under Regulation 2016/426 (pre-exit), continues to have effect as it did immediately before IP completion day, in relation to that appliance or fitting.
- 3 Paragraph 2 does not apply to—

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- a any obligation of the enforcement authority to inform the European Commission or the member States of any matter, or
  - b any obligation to take action outside of the United Kingdom in respect of that appliance or fitting.
- 4 Where during the pre-exit period—
- a an appliance or fitting has not been placed on the market; and
  - b a manufacturer has taken any action under Article 14 of Regulation 2016/426 (pre-exit) in relation to that appliance or fitting,
- that action has effect as if it had been done under Article 14 of this Regulation.
- [<sup>F165</sup> Subject to paragraph 6, where before 11pm on 31st December 2024—
- a an appliance or fitting has not been placed on the market; and
  - b a manufacturer has taken any action under the conformity assessment procedure that applies to that appliance or fitting in accordance with Article 14 of Regulation 2016/426 (pre-exit)
- that action has effect as if it had been done under the applicable conformity assessment procedure referred to in Article 14 of this Regulation.
- 6 Paragraph 5 does not apply—
- a after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and
  - b in any event, after 31st December 2027.]]

#### Textual Amendments

- F164** Art. 44 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(41)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2 and [S.I. 2020/852](#), regs. 2(2), 4(2), [Sch. 1 para. 1\(v\)\(vi\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F165** Art. 44(5)(6) inserted (E.W.S.) (31.12.2022) by [The Product Safety and Metrology \(Amendment and Transitional Provisions\) Regulations 2022 \(S.I. 2022/1393\)](#), regs. 1(1), **22(2)**

#### <sup>F166</sup> Article 45

#### Repeal

#### Textual Amendments

- F166** Art. 45 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(42)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

#### <sup>F167</sup> Article 46

#### Entry into force and application

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

### Textual Amendments

**F167** Art. 46 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(42)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F168**  
...

**F169**  
...

**F170**  
...

### Textual Amendments

**F168** Words in Signature omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(43)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F169** Words in Signature omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(43)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F170** Words in Signature omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(43)(c)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

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## ANNEX I

### ESSENTIAL REQUIREMENTS

#### PRELIMINARY OBSERVATIONS:

1. The essential requirements laid down in this Regulation are compulsory.
2. The essential requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture as well as technical and economic considerations which are consistent with a high degree of energy efficiency and of health and safety protection.

#### 1. GENERAL REQUIREMENTS

- 1.1. Appliances shall be so designed and constructed as to operate safely and present no danger to persons, domestic animals or property, when normally used.

Fittings shall be so designed and constructed as to fulfil correctly their intended purpose when incorporated into an appliance or assembled to constitute an appliance.

- 1.2. The manufacturer is under an obligation to analyse the risks in order to identify those which apply to his appliance or fitting. He shall then design and construct it taking into account its risk assessment.
- 1.3. In selecting the most appropriate solutions, the manufacturer shall apply the principles set out below, in the following order:
  - (a) eliminate or reduce risks as far as possible (inherently safe design and construction);
  - (b) take the necessary protection measures in relation to risks that cannot be eliminated;
  - (c) inform users of the residual risks due to any shortcomings of the protection measures adopted and indicate whether any particular precautions are required.
- 1.4. When designing and constructing the appliance, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the appliance, but also the reasonably foreseeable uses.
- 1.5. All appliances shall:
  - (a) be accompanied by instructions for installation intended for the installer;
  - (b) be accompanied by instructions for use and servicing, intended for the user;
  - (c) bear appropriate warning notices, which shall also appear on the packaging.
- 1.6.1. The instructions for installation intended for the installer shall contain all the instructions for installation, adjustment and servicing required to ensure that those operations are correctly performed so that the appliance may be used safely.

The instructions for installation intended for the installer shall include also information on the technical specifications of the interface between the appliance and its installation environment allowing its correct connection to the gas supply network, the supply of auxiliary energy, the combustion air supply and the flue gas evacuation system.

- 1.6.2. The instructions for use and servicing intended for the user shall contain all the information required for safe use and in particular shall draw the user's attention to any restrictions on use.

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The manufacturers shall note in the instructions where additional care is needed or where it would be advisable that any of the above work be carried out by a professional. This shall be without prejudice to national requirements to that effect.

The manufacturer of the appliance shall include in the instructions accompanying the appliance all necessary information for adjustment, operation and maintenance of the fittings as part of the finished appliance, as appropriate.

- 1.6.3. The warning notices on the appliance and its packaging shall clearly state the type of gas to be used, the gas supply pressure, the appliance category and any restrictions on use, in particular the restriction whereby the appliance shall be installed only in areas where there is sufficient ventilation so as to ensure that the risks presented by it are minimised.
- 1.7. The instructions for incorporation of the fitting into an appliance or its assembly in order to constitute an appliance and for its adjustment, operation and maintenance shall be provided with the fittings concerned as part of the <sup>F171</sup>... declaration of conformity.

#### Textual Amendments

**F171** Word in Annex 1 para. 1.7 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(44\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1))

## 2. MATERIALS

Materials for appliances or fittings shall be appropriate for their intended purpose and shall withstand the mechanical, chemical and thermal conditions to which they will foreseeably be subjected.

## 3. DESIGN AND CONSTRUCTION

The obligations arising for appliances from the essential requirements set out in this point apply also to fittings, as far as relevant.

- 3.1. General
  - 3.1.1. Appliances shall be so designed and constructed that, when normally used, no instability, distortion, breakage or wear likely to impair their safety may occur.
  - 3.1.2. Condensation produced at the start-up and/or during use shall not affect the safety of appliances.
  - 3.1.3. Appliances shall be so designed and constructed as to minimise the risk of explosion in the event of a fire of external origin.
  - 3.1.4. Appliances shall be so designed and constructed that water and inappropriate air penetration into the gas circuit does not occur.
  - 3.1.5. In the event of a normal fluctuation of auxiliary energy, appliances shall continue to operate safely.
  - 3.1.6. Abnormal fluctuation or failure of auxiliary energy or its restoration shall not lead to an unsafe situation.
  - 3.1.7. Appliances shall be so designed and constructed as to obviate any gas-related risks due to hazards of electrical origin. As far as relevant, the results of the conformity

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assessment in relation to the safety requirements of [F172the Radio Equipment Regulations 2017] or the safety objectives of [F173the Electrical Equipment (Safety) Regulations 2016] shall be taken into account.

#### Textual Amendments

**F172** Words in Annex 1 para. 3.1.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F173** Words in Annex 1 para. 3.1.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(b)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.1.8. Appliances shall be so designed and constructed as to obviate any gas-related risks due to hazards originating from electromagnetic phenomena. As far as relevant, the results of the conformity assessment in relation to the electromagnetic compatibility requirements of [F174the Radio Equipment Regulations 2017] or [F175the Electromagnetic Compatibility Regulations 2016] shall be taken into account.

#### Textual Amendments

**F174** Words in Annex 1 para. 3.1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(c)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F175** Words in Annex 1 para. 3.1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(c)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.1.9. All pressurised parts of an appliance shall withstand the mechanical and thermal stresses to which they are subjected without any deformation affecting safety.
- 3.1.10. Appliances shall be so designed and constructed that failure of a safety, controlling or regulating device may not lead to an unsafe situation.
- 3.1.11. If an appliance is equipped with safety and controlling devices, the functioning of the safety devices shall not be overruled by that of the controlling devices.
- 3.1.12. All parts of appliances which are set or adjusted at the stage of manufacture and which should not be manipulated by the user or the installer shall be appropriately protected.
- 3.1.13. Levers and other controlling and setting devices shall be clearly marked and give appropriate instructions so as to prevent any error in operation/use. Their design shall be such as to preclude accidental operation.
- 3.2. Unburned gas release
- 3.2.1. Appliances shall be so designed and constructed that the gas leakage rate is not dangerous.
- 3.2.2. Appliances shall be so designed and constructed that gas release at any state of operation is limited in order to avoid a dangerous accumulation of unburned gas in the appliance.

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3.2.3. Appliances intended to be used in indoor spaces and rooms shall be so designed and constructed as to prevent the release of unburned gas in all situations which could lead to a dangerous accumulation of unburned gas in such spaces and rooms.

3.2.4. Appliances designed and constructed to burn gas containing carbon monoxide or other toxic components shall not present a danger to the health of persons and domestic animals exposed.

### 3.3. Ignition

Appliances shall be so designed and constructed that, when normally used, ignition and re-ignition is smooth and cross-lighting is assured.

### 3.4. Combustion

3.4.1. Appliances shall be so designed and constructed that, when normally used, the combustion process is stable and combustion products do not contain unacceptable concentrations of substances harmful to health.

3.4.2. Appliances shall be so designed and constructed that, when normally used, there will be no accidental release of combustion products.

3.4.3. Appliances connected to a flue for the dispersal of combustion products shall be so designed and constructed that in abnormal draught conditions there is no release of combustion products in a dangerous quantity into the indoor spaces or rooms concerned.

3.4.4. Appliances shall be so designed and constructed that, when normally used, they do not cause a concentration of carbon monoxide or other substances harmful to health, such as they would be likely to present a danger to the health of persons and domestic animals exposed.

### 3.5. Rational use of energy

Appliances shall be so designed and constructed as to ensure rational use of energy, reflecting the state of the art and taking into account safety aspects.

### 3.6. Temperature

3.6.1. Parts of appliances which are intended to be installed or placed in close proximity to surfaces shall not reach temperatures which present a danger.

3.6.2. The surface temperature of parts of appliances intended to be handled during normal use shall not present a danger to the user.

3.6.3. The surface temperatures of external parts of appliances, with the exception of surfaces or parts which are associated with the transmission of heat, shall not under operating conditions present a danger to the health and safety of persons exposed and in particular to children and elderly people, for whom an appropriate reaction time shall be taken into account.

### 3.7. Contact with food and water intended for human consumption

Without prejudice to Regulations (EC) No 1935/2004<sup>(14)</sup> and (EU) No 305/2011<sup>(15)</sup> of the European Parliament and of the Council, materials and parts used in the construction of an appliance which may come into contact with food or water intended for human consumption

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as defined in Article 2 of Council Directive 98/83/EC<sup>(16)</sup>, shall not impair quality of the food or water.

## ANNEX II

### CONTENT<sup>F176</sup> ... OF THE GAS SUPPLY CONDITIONS [<sup>F177</sup>TO BE PUBLISHED UNDER ARTICLE 4]

#### Textual Amendments

**F176** Words in Annex 2 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F177** Words in Annex 2 heading inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. [<sup>F178</sup>The Secretary of State must provide the following content in the information that is published under Article 4]:

(a)	(i)	gross calorific value (GCV) in MJ/m <sup>3</sup>	minimum/maximum;
	(ii)	Wobbe index in MJ/m <sup>3</sup>	minimum/maximum.
(b)	Gas composition by volume in % of the total content:		
	—	C <sub>1</sub> to C <sub>5</sub> content in % (sum)	minimum/maximum;
	—	N <sub>2</sub> + CO <sub>2</sub> content in %	minimum/maximum;
	—	CO content in %	minimum/maximum;
	—	unsaturated HC content in %	minimum/maximum;
	—	hydrogen content in %	minimum/maximum.
(c)	Information on toxic components contained in the gaseous fuel.		

That communication shall also include either of the following:

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

(a)	supply pressure at the inlet of appliances in mbar:	nominal/minimum/maximum;
(b)	(i) supply pressure at the point of delivery in mbar:	nominal/minimum/maximum;
	(ii) admissible pressure loss in the end-user gas installation in mbar:	nominal/minimum/maximum.

#### Textual Amendments

**F178** Words in Annex 2 para. 1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2. The reference conditions for Wobbe index and gross calorific value shall be the following:

(a)	combustion reference temperature:	15 °C;
(b)	volume measurement reference temperature:	15 °C;
(c)	volume measurement reference pressure:	1 013,25 mbar.

### ANNEX III

#### CONFORMITY ASSESSMENT PROCEDURES FOR APPLIANCES AND FITTINGS

1. MODULE B: <sup>F179</sup>... TYPE-EXAMINATION — PRODUCTION TYPE
- 1.1. <sup>F180</sup>... type-examination is the part of a conformity assessment procedure in which [<sup>F181</sup>an approved] body examines the technical design of an appliance or a fitting and verifies and attests that the technical design of the appliance or the fitting meets the requirements of this Regulation that apply to it.

#### Textual Amendments

**F180** Word in Annex 3 para. 1.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F181** Words in Annex 3 para. 1.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- 1.2. <sup>F182</sup>... type-examination shall be carried out by assessment of the adequacy of the technical design of the appliance or the fitting through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a specimen, representative of the production envisaged, of the complete appliance or fitting (production type).

#### Textual Amendments

**F182** Word in Annex 3 para. 1.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3. The manufacturer shall lodge an application for <sup>F183</sup>... type-examination with [<sup>F184</sup>a single approved] body of his choice.

#### Textual Amendments

**F183** Word in Annex 3 para. 1.3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F184** Words in Annex 3 para. 1.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3.1. The application shall include the following:
- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other [<sup>F185</sup>approved] body;
  - (c) the technical documentation. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting. The technical documentation shall contain, wherever applicable, at least the following elements:
    - (1) a general description of the appliance or the fitting;
    - (2) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
    - (3) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
    - (4) a list of the [<sup>F186</sup>designated] standards applied in full or in part <sup>F187</sup>... and, where those [<sup>F186</sup>designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event

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- of partly applied [<sup>F186</sup>designated] standards, the technical documentation shall specify the parts which have been applied;
- (5) results of design calculations made, examinations carried out, etc.;
  - (6) test reports;
  - (7) instructions for installation and use of the appliance;
  - (8) the <sup>F188</sup>... declaration of conformity of the fitting containing the instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance;
- (d) the specimens representative of the production envisaged. The [<sup>F189</sup>approved] body may request further specimens where needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant [<sup>F190</sup>designated] standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

#### Textual Amendments

- F185** Word in Annex 3 para. 1.3.1(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F186** Word in Annex 3 para. 1.3.1(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F187** Words in Annex 3 para. 1.3.1(c) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F188** Word in Annex 3 para. 1.3.1(c) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F189** Word in Annex 3 para. 1.3.1(d) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F190** Word in Annex 3 para. 1.3.1(e) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3.2. Where appropriate, the manufacturer shall also submit to the [<sup>F191</sup>approved] body the following documents:

#### Textual Amendments

- F191** Word in Annex 3 para. 1.3.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



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- (a) the <sup>F192</sup>... type-examination certificate and the <sup>F192</sup>... declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance or the fitting;
- (c) any other document making it possible for the [<sup>F191</sup>approved] body to improve its assessment.

#### Textual Amendments

**F192** Word in Annex 3 para. 1.3.2(a) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.4. The [<sup>F193</sup>approved] body shall:

#### Textual Amendments

**F193** Word in Annex 3 para. 1.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

For the appliance or the fitting:

- 1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the appliance or the fitting.

For the specimen(s):

- 1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant [<sup>F194</sup>designated] standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant [<sup>F195</sup>designated] standards, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant [<sup>F196</sup>designated] standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;
- 1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

#### Textual Amendments

**F194** Word in Annex 3 para. 1.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

**F195** Word in Annex 3 para. 1.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F196** Word in Annex 3 para. 1.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.5. The <sup>F197</sup>approved] body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the <sup>F198</sup>Secretary of State], the <sup>F197</sup>approved] body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

#### Textual Amendments

**F197** Word in Annex 3 para. 1.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F198** Words in Annex 3 para. 1.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(g)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.6. Where the appliance or the fitting type meets the requirements of this Regulation, the <sup>F199</sup>approved] body shall issue <sup>F200</sup>a] type-examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning. The certificate may have one or more annexes attached.

#### Textual Amendments

**F199** Word in Annex 3 para. 1.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F200** Word in Annex 3 para. 1.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(h)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The <sup>F201</sup>... type-examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured appliances or fittings with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

#### Textual Amendments

**F201** Word in Annex 3 para. 1.6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

The certificate shall have a maximum validity period of ten years from the date of its issue.

Where the type does not satisfy the applicable requirements of this Regulation, the [F<sup>199</sup>approved] body shall refuse to issue [F<sup>200</sup>a] type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The [F<sup>202</sup>approved] body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Regulation, and shall determine whether such changes require further investigation. If so, the [F<sup>202</sup>approved] body shall inform the manufacturer accordingly.

#### Textual Amendments

**F202** Word in Annex 3 para. 1.7 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall inform the [F<sup>202</sup>approved] body that holds the technical documentation relating to the F<sup>203</sup>... type-examination certificate of all modifications to the approved type that may affect the conformity of the appliance or the fitting with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original F<sup>203</sup>... type-examination certificate.

#### Textual Amendments

**F203** Word in Annex 3 para. 1.7 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.8. Each [F<sup>204</sup>approved] body shall inform [F<sup>205</sup>the Secretary of State] concerning the F<sup>206</sup>... type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to [F<sup>205</sup>the Secretary of State] the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

#### Textual Amendments

**F204** Word in Annex 3 para. 1.8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F205** Words in Annex 3 para. 1.8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(i)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

**F206** Word in Annex 3 para. 1.8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [F<sup>204</sup>approved] body shall inform the other [F<sup>204</sup>approved] bodies concerning the F<sup>206</sup>... type-examination certificates and/or any additions thereto which it has refused, withdrawn,

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suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

[<sup>F207</sup>The Secretary of State] and the other [<sup>F204</sup>approved] bodies may, on request, obtain a copy of the <sup>F206</sup>... type-examination certificates and/or additions thereto. On request, the [<sup>F208</sup>Secretary of State] may obtain a copy of the technical documentation and the results of the examinations carried out by the [<sup>F204</sup>approved] body. The [<sup>F204</sup>approved] body shall keep a copy of the <sup>F206</sup>... type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

#### Textual Amendments

**F207** Words in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(i)(ii)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F208** Words in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(i)(ii)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.9. The manufacturer shall keep a copy of the <sup>F209</sup>... type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the [<sup>F210</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

#### Textual Amendments

**F209** Word in Annex 3 para. 1.9 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F210** Words in Annex 3 para. 1.9 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(j)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

#### Textual Amendments

**F179** Word in Annex 3 para. 1 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2. MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS
- 2.1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the appliances or the fittings

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concerned are in conformity with the type described in the <sup>F211</sup>... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

#### Textual Amendments

**F211** Word in Annex 3 para. 2.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(k\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### 2.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances or fittings with the type described in the <sup>F212</sup>... type-examination certificate and with the requirements of this Regulation that apply to them.

#### Textual Amendments

**F212** Word in Annex 3 para. 2.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(k\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### 2.3. Product checks

[<sup>F213</sup>An approved] body, chosen by the manufacturer, shall carry out product checks or have them carried out at intervals of one year or less, in order to verify the quality of the internal checks on the appliance or the fitting, taking into account, inter alia, the technological complexity of the appliances or the fittings and the quantity of production. An adequate sample of the final appliances or fittings taken on site by [<sup>F214</sup>the approved] body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the [<sup>F215</sup>designated] standards, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation. Where a sample does not conform to the acceptable quality level, [<sup>F214</sup>the approved] body shall take appropriate measures.

#### Textual Amendments

**F213** Words in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(l\)\(i\)\(aa\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F214** Words in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(l\)\(i\)\(bb\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F215** Word in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(l\)\(i\)\(cc\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the appliance or the fitting performs within acceptable limits, with a view to ensuring conformity of the appliance or the fitting.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

The manufacturer shall, under the responsibility of the [F<sup>216</sup>approved] body, affix the [F<sup>216</sup>approved] body's identification number during the manufacturing process.

#### Textual Amendments

**F216** Word in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(l)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.4. [F<sup>217</sup>UK] marking and F<sup>218</sup>... declaration of conformity

2.4.1. The manufacturer shall affix the [F<sup>219</sup>UK] marking to each individual appliance or fitting that is in conformity with the type described in the F<sup>220</sup>... type-examination certificate and satisfies the applicable requirements of this Regulation.

#### Textual Amendments

**F219** Word in Annex 3 para. 2.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(m)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F220** Word in Annex 3 para. 2.4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.4.2. The manufacturer shall draw up a written F<sup>221</sup>... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [F<sup>222</sup>enforcement authority] for 10 years after the appliance or fitting has been placed on the market. The F<sup>221</sup>... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

#### Textual Amendments

**F221** Word in Annex 3 para. 2.4.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F222** Words in Annex 3 para. 2.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(n)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the F<sup>221</sup>... declaration of conformity shall be made available to the [F<sup>223</sup>enforcement authority] upon request. A copy of the F<sup>221</sup>... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

#### Textual Amendments

**F223** Words in Annex 3 para. 2.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(n)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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#### Textual Amendments

- F217** Word in Annex 3 para. 2.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(m)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F218** Word in Annex 3 para. 2.4 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 2.5. Authorised representative

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### 3. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

- 3.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2 and 3.5, and ensures and declares on his sole responsibility that the appliances or fittings concerned are in conformity with the type described in the <sup>F224</sup>... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

#### Textual Amendments

- F224** Word in Annex 3 para. 3.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 3.2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the appliances or fittings concerned as specified in point 3.3, and shall be subject to surveillance as specified in point 3.4.

#### 3.3. Quality system

- 3.3.1. The manufacturer shall lodge an application for assessment of his quality system with the [<sup>F225</sup>approved] body of his choice, for the appliances or fittings concerned.

#### Textual Amendments

- F225** Word in Annex 3 para. 3.3.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

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- (b) a written declaration that the same application has not been lodged with any other [<sup>F225</sup>approved] body;
- (c) all relevant information for the appliance or the fitting approved under module B;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the <sup>F226</sup>... type-examination certificate.

#### Textual Amendments

**F226** Word in Annex 3 para. 3.3.1(e) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.3.2. The quality system shall ensure that the appliances or fittings are in conformity with the type described in the <sup>F227</sup>... type-examination certificate and comply with the requirements of this Regulation that apply to them.

#### Textual Amendments

**F227** Word in Annex 3 para. 3.3.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

- 3.3.3. The [<sup>F228</sup>approved] body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.3.2.



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F228** Word in Annex 3 para. 3.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant [<sup>F229</sup>designated] standard.

#### Textual Amendments

**F229** Word in Annex 3 para. 3.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(q)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and the product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.3.1(e), to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the appliance or the fitting with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.3.5. The manufacturer shall keep the [<sup>F230</sup>approved] body that has approved the quality system informed of any intended change to the quality system.

#### Textual Amendments

**F230** Word in Annex 3 para. 3.3.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The [<sup>F230</sup>approved] body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. Surveillance under the responsibility of the [<sup>F231</sup>approved] body
- 3.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- 3.4.2. The manufacturer shall, for assessment purposes, allow the [<sup>F232</sup>approved] body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

**Textual Amendments**

**F232** Word in Annex 3 para. 3.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 3.4.3. The [<sup>F233</sup>approved] body shall carry out periodic audits at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

**Textual Amendments**

**F233** Word in Annex 3 para. 3.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.4.4. In addition, the [<sup>F234</sup>approved] body may pay unexpected visits to the manufacturer. During such visits the [<sup>F234</sup>approved] body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The [<sup>F234</sup>approved] body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**Textual Amendments**

**F234** Word in Annex 3 para. 3.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**Textual Amendments**

**F231** Word in Annex 3 para. 3.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.5. [<sup>F235</sup>UK] marking and <sup>F236</sup>... declaration of conformity
- 3.5.1. The manufacturer shall affix the [<sup>F237</sup>UK] marking and, under the responsibility of the [<sup>F238</sup>approved] body referred to in point 3.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

the <sup>F239</sup> ... type-examination certificate and satisfies the applicable requirements of this Regulation.

#### Textual Amendments

- F237** Word in Annex 3 para. 3.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(r)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F238** Word in Annex 3 para. 3.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F239** Word in Annex 3 para. 3.5.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

3.5.2. The manufacturer shall draw up a written <sup>F240</sup> ... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [<sup>F241</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The <sup>F240</sup> ... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

#### Textual Amendments

- F240** Word in Annex 3 para. 3.5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F241** Words in Annex 3 para. 3.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(s)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the <sup>F240</sup> ... declaration of conformity shall be made available to the [<sup>F242</sup>enforcement authority] upon request. A copy of the <sup>F240</sup> ... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

#### Textual Amendments

- F242** Words in Annex 3 para. 3.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(s)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

- F235** Word in Annex 3 para. 3.5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(r)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F236** Word in Annex 3 para. 3.5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- 3.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the [F243 enforcement authority]:

#### Textual Amendments

**F243** Words in Annex 3 para. 3.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(t)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the documentation referred to in point 3.3.1;
- (b) the information relating to the change referred to in point 3.3.5, as approved;
- (c) the decisions and reports of the [F244 approved] body referred to in points 3.3.5, 3.4.3 and 3.4.4.

#### Textual Amendments

**F244** Word in Annex 3 para. 3.6(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.7. Each [F245 approved] body shall inform [F246 the Secretary of State] of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to [F246 the Secretary of State] the list of quality systems approvals refused, suspended or otherwise restricted.

#### Textual Amendments

**F245** Word in Annex 3 para. 3.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F246** Words in Annex 3 para. 3.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(u)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [F245 approved] body shall inform the other [F245 approved] bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

- 3.8. Authorised representative

The manufacturer's obligations set out in points 3.3.1, 3.3.5, 3.5 and 3.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE

- 4.1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

in points 4.2 and 4.5, and ensures and declares on his sole responsibility that the appliances or fittings concerned are in conformity with the type described in the <sup>F247</sup> ... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

#### Textual Amendments

**F247** Word in Annex 3 para. 4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 4.2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the appliances or fittings concerned as specified in point 4.3 and shall be subject to surveillance as specified in point 4.4.

#### 4.3. Quality system

4.3.1. The manufacturer shall lodge an application for assessment of his quality system with the [<sup>F248</sup>approved] body of his choice, for the appliances or fittings concerned.

#### Textual Amendments

**F248** Word in Annex 3 para. 4.3.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other [<sup>F248</sup>approved] body;
- (c) all relevant information for the product category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the <sup>F249</sup> ... type-examination certificate.

#### Textual Amendments

**F249** Word in Annex 3 para. 4.3.1(e) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.3.2. The quality system shall ensure compliance of the appliances or the fittings with the type described in the <sup>F250</sup> ... type-examination certificate and with the applicable requirements of this Regulation.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F250** Word in Annex 3 para. 4.3.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (d) the means of monitoring the effective operation of the quality system.

4.3.3. The [<sup>F251</sup>approved] body shall assess the quality system to determine whether it satisfies the requirements referred to in point 4.3.2.

#### Textual Amendments

**F251** Word in Annex 3 para. 4.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant [<sup>F252</sup>designated] standard.

#### Textual Amendments

**F252** Word in Annex 3 para. 4.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(x)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 4.3.1(e), in order to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the appliance or the fitting with those requirements.

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 4.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 4.3.5. The manufacturer shall keep the [F253 approved] body that has approved the quality system informed of any intended change to the quality system.

#### Textual Amendments

**F253** Word in Annex 3 para. 4.3.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The [F253 approved] body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 4.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 4.4. Surveillance under the responsibility of the [F254 approved] body
- 4.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.4.2. The manufacturer shall, for assessment purposes, allow the [F255 approved] body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

#### Textual Amendments

**F255** Word in Annex 3 para. 4.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.4.3. The [F256 approved] body shall carry out periodic audits at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

#### Textual Amendments

**F256** Word in Annex 3 para. 4.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- 4.4.4. In addition, the [<sup>F257</sup>approved] body may pay unexpected visits to the manufacturer. During such visits the [<sup>F257</sup>approved] body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The [<sup>F257</sup>approved] body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### Textual Amendments

**F257** Word in Annex 3 para. 4.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

**F254** Word in Annex 3 para. 4.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 4.5. [<sup>F258</sup>UK] marking and <sup>F259</sup>... declaration of conformity
- 4.5.1. The manufacturer shall affix the [<sup>F260</sup>UK] marking and, under the responsibility of the [<sup>F261</sup>approved] body referred to in point 4.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in the <sup>F262</sup>... type-examination certificate and satisfies the applicable requirements of this Regulation.

#### Textual Amendments

**F260** Word in Annex 3 para. 4.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(y)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F261** Word in Annex 3 para. 4.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F262** Word in Annex 3 para. 4.5.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 4.5.2. The manufacturer shall draw up a written <sup>F263</sup>... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [<sup>F264</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The <sup>F263</sup>... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

#### Textual Amendments

**F263** Word in Annex 3 para. 4.5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

**F264** Words in Annex 3 para. 4.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(z)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the <sup>F263</sup>... declaration of conformity shall be made available to the [<sup>F265</sup>enforcement authority] upon request. A copy of the <sup>F263</sup>... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

#### Textual Amendments

**F265** Words in Annex 3 para. 4.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(z)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

**F258** Word in Annex 3 para. 4.5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(y)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F259** Word in Annex 3 para. 4.5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the [<sup>F266</sup>enforcement authority]:

#### Textual Amendments

**F266** Words in Annex 3 para. 4.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(aa)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the documentation referred to in point 4.3.1;
- (b) the information relating to the change referred to in point 4.3.5, as approved;
- (c) the decisions and reports of the [<sup>F267</sup>approved] body referred to in points 4.3.5, 4.4.3 and 4.4.4.

#### Textual Amendments

**F267** Word in Annex 3 para. 4.6(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.7. Each [<sup>F268</sup>approved] body shall inform [<sup>F269</sup>the Secretary of State] of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to [<sup>F269</sup>the Secretary of State] the list of quality system approvals refused, suspended or otherwise restricted.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

- F268** Word in Annex 3 para. 4.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F269** Words in Annex 3 para. 4.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [<sup>F268</sup>approved] body shall inform the other [<sup>F268</sup>approved] bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

#### 4.8. Authorised representative

The manufacturer's obligations set out in points 4.3.1, 4.3.5, 4.5 and 4.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### 5. MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

- 5.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.5.1 and 5.6, and ensures and declares on his sole responsibility that the appliances or fittings concerned, which have been subject to point 5.3, are in conformity with the type described in the <sup>F270</sup>... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

#### Textual Amendments

- F270** Word in Annex 3 para. 5.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 5.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances or fittings with the approved type described in the <sup>F271</sup>... type-examination certificate and with the requirements of this Regulation that apply to them.

#### Textual Amendments

- F271** Word in Annex 3 para. 5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 5.3. Verification

[<sup>F272</sup>An approved] body chosen by the manufacturer shall carry out appropriate examinations and tests, or have them carried out, in order to check the conformity of the appliances or fittings with

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

the approved type described in the <sup>F273</sup>... type-examination certificate and with the appropriate requirements of this Regulation.

#### Textual Amendments

**F272** Words in Annex 3 para. 5.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(dd)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F273** Word in Annex 3 para. 5.3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The examinations and tests to check the conformity of the appliances or fittings with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every appliance or fitting as specified in point 5.4 or by examination and testing of the appliances or fittings on a statistical basis as specified in point 5.5.

5.4. Verification of conformity by examination and testing of every appliance or fitting

5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant [<sup>F274</sup>designated] standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the <sup>F275</sup>... type-examination certificate and with the appropriate requirements of this Regulation.

#### Textual Amendments

**F274** Word in Annex 3 para. 5.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ee)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F275** Word in Annex 3 para. 5.4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

In the absence of such a [<sup>F274</sup>designated] standard, the [<sup>F276</sup>approved] body concerned shall decide on the appropriate tests to be carried out.

#### Textual Amendments

**F276** Word in Annex 3 para. 5.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.4.2. The [<sup>F277</sup>approved] body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved appliance or fitting, or have it affixed under its responsibility.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F277** Word in Annex 3 para. 5.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the certificates of conformity available for inspection by the [<sup>F278</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

#### Textual Amendments

**F278** Words in Annex 3 para. 5.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(gg)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### 5.5. Statistical verification of conformity

5.5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his appliances or fittings for verification in the form of homogeneous lots.

5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant [<sup>F279</sup>designated] standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a [<sup>F279</sup>designated] standard, the [<sup>F280</sup>approved] body concerned shall decide on the appropriate tests to be carried out.

#### Textual Amendments

**F279** Word in Annex 3 para. 5.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ee)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F280** Word in Annex 3 para. 5.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.5.3. The [<sup>F281</sup>approved] body shall apply a sampling system with the following characteristics:

#### Textual Amendments

**F281** Word in Annex 3 para. 5.5.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,5 % and 1,5 %,
  - a limit quality corresponding to a probability of acceptance of 5 % with a non-conformity percentage of between 5 % and 10 %.
- 5.5.4. If a lot is accepted, all appliances or fittings of the lot shall be considered approved, except for those appliances or fittings from the sample that have been found not to satisfy the tests.

The [F<sup>282</sup>approved] body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved appliance or fitting, or have it affixed under its responsibility.

#### Textual Amendments

**F282** Word in Annex 3 para. 5.5.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the certificates of conformity at the disposal of the [F<sup>283</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

#### Textual Amendments

**F283** Words in Annex 3 para. 5.5.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(hh)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.5.5. If a lot is rejected, the [F<sup>284</sup>approved] body or the [F<sup>285</sup>enforcement authority] shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots the [F<sup>284</sup>approved] body may suspend the statistical verification and take appropriate measures.

#### Textual Amendments

**F284** Word in Annex 3 para. 5.5.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F285** Words in Annex 3 para. 5.5.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.6. [F<sup>286</sup>UK] marking and F<sup>287</sup>... declaration of conformity
- 5.6.1. The manufacturer shall affix the [F<sup>288</sup>UK] marking and, under the responsibility of the [F<sup>289</sup>approved] body referred to in point 5.3, the latter's identification number to each individual appliance or fitting that is in conformity with the approved type described in the F<sup>290</sup>... type-examination certificate and satisfies the applicable requirements of this Regulation.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

- F288** Word in Annex 3 para. 5.6.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(jj)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F289** Word in Annex 3 para. 5.6.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F290** Word in Annex 3 para. 5.6.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.6.2. The manufacturer shall draw up a written <sup>F291</sup>... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [<sup>F292</sup>enforcement authority], for 10 years after the appliance or the fitting has been placed on the market. The <sup>F291</sup>... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

#### Textual Amendments

- F291** Word in Annex 3 para. 5.6.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F292** Words in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(kk)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the <sup>F291</sup>... declaration of conformity shall be made available to the [<sup>F293</sup>enforcement authority] upon request. A copy of the <sup>F291</sup>... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

#### Textual Amendments

- F293** Words in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(kk)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

If the [<sup>F294</sup>approved] body referred to in point 5.3 agrees and under its responsibility, the manufacturer may also affix the [<sup>F294</sup>approved] body's identification number to the appliance or the fitting.

#### Textual Amendments

- F294** Word in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

- F286** Word in Annex 3 para. 5.6 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(jj)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F287** Word in Annex 3 para. 5.6 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.7. If the [<sup>F295</sup>approved] body agrees and under its responsibility, the manufacturer may affix the [<sup>F295</sup>approved] body's identification number to the appliances or the fittings during the manufacturing process.

#### Textual Amendments

- F295** Word in Annex 3 para. 5.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2 and 5.5.1.

## 6. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

- 6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the appliance or the fitting concerned, which has been subject to point 6.4, is in conformity with the requirements of this Regulation that apply to it.

### 6.2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the [<sup>F296</sup>approved] body referred to in point 6.4. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting.

#### Textual Amendments

- F296** Word in Annex 3 para. 6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 6.2.1. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the appliance or the fitting;

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
- (d) a list of the [F297designated] standards applied in full or in part F298 ..., and, where those [F297designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied [F297designated] standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports;
- (g) instructions for installation and use, for appliances;
- (h) instructions for incorporation into an appliance or for assembly, for fittings.

#### Textual Amendments

**F297** Word in Annex 3 para. 6.2.1(d) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(mm)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F298** Words in Annex 3 para. 6.2.1(d) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(mm)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 6.2.2. Where appropriate, the manufacturer shall also submit to the [F299approved] body the following documents:

#### Textual Amendments

**F299** Word in Annex 3 para. 6.2.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the F300 ... type-examination certificate and the F300 ... declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and inspection and monitoring of the appliance or the fitting;
- (c) any other document making it possible for the [F301approved] body to improve its assessment.

#### Textual Amendments

**F300** Word in Annex 3 para. 6.2.2(a) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)



*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

**F301** Word in Annex 3 para. 6.2.2(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(II)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the technical documentation at the disposal of the [<sup>F302</sup>enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

#### Textual Amendments

**F302** Words in Annex 3 para. 6.2.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(oo)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### 6.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances or fittings with the applicable requirements of this Regulation.

### 6.4. Verification

[<sup>F303</sup>An approved] body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant [<sup>F304</sup>designated] standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them carried out. In the absence of such a [<sup>F304</sup>designated] standard [<sup>F305</sup>the approved] body concerned shall decide on the appropriate tests to be carried out.

#### Textual Amendments

**F303** Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F304** Word in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F305** Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

If deemed necessary by the [<sup>F306</sup>approved] body, the examinations and tests may be carried out after the incorporation of the fitting, the assembly or the installation of the appliance.

#### Textual Amendments

**F306** Word in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(II)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

The [F306 approved] body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved appliances or fittings, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the [F307 enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

#### Textual Amendments

**F307** Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.5. [F308UK] marking and F309... declaration of conformity

6.5.1. The manufacturer shall affix the [F310UK] marking and, under the responsibility of the [F311 approved] body referred to in point 6.4, the latter's identification number to each appliance or fitting that satisfies the applicable requirements of this Regulation.

#### Textual Amendments

**F310** Word in Annex 3 para. 6.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(qq)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F311** Word in Annex 3 para. 6.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.5.2. The manufacturer shall draw up a written F312... declaration of conformity and keep it at the disposal of the [F313 enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The F312... declaration of conformity shall identify the appliance or the fitting for which it has been drawn up.

#### Textual Amendments

**F312** Word in Annex 3 para. 6.5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F313** Words in Annex 3 para. 6.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(rr)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the F312... declaration of conformity shall be made available to the [F314 enforcement authority] upon request. A copy of the F312... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

#### Textual Amendments

**F314** Words in Annex 3 para. 6.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(rr)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

**F308** Word in Annex 3 para. 6.5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(qq)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F309** Word in Annex 3 para. 6.5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

### 6.6. Authorised representative

The manufacturer's obligations set out in points 6.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## ANNEX IV

### INSCRIPTIONS

1. In addition to the [<sup>F315</sup>UK] marking referred to in Article 16, the appliance or its data plate shall bear the following information:
  - (a) the manufacturer's name, registered trade name or registered trade mark;
  - (b) the appliance type, batch or serial number of the appliance or other element allowing its identification;
  - (c) the type of electrical supply used, where applicable;
  - (d) the appliance category marking;
  - (e) the nominal supply pressure for the appliance;
  - (f) the necessary information to ensure correct and safe installation, according to the nature of the appliance.

#### Textual Amendments

**F315** Word in Annex 4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(47)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2. The fitting or its data plate shall bear, as far as relevant, the information provided for in point 1.

*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

## ANNEX V

### F316 ... DECLARATION OF CONFORMITY No ...<sup>(17)</sup>

#### Textual Amendments

**F316** Word in Annex 5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. Appliance or fitting /appliance or fitting model (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the appliance or fitting allowing traceability; where necessary for the identification of the appliance or the fitting, an image may be included): description of the appliance or the fitting.
5. The object of the declaration described in point 4 is in conformity with the relevant [<sup>F317</sup>statutory requirements]: ... <sup>F318</sup>....

#### Textual Amendments

**F317** Words in Annex 5 para. 5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

**F318** Words in Annex 5 para. 5 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(b)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6. References to the relevant [<sup>F319</sup>designated] standards used or references to the other technical specifications in relation to which conformity is declared:

#### Textual Amendments

**F319** Word in Annex 5 para. 6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(c)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

7. The [<sup>F320</sup>approved] body ... (name, address, number) ... performed ... (description of intervention) ... and issued the certificate(s): ... (details, including its date, and, where appropriate, information on the duration and conditions of its validity).

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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

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**Textual Amendments**

**F320** Word in Annex 5 para. 7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

8. In the case of fittings, instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance in order to assist compliance with the essential requirements applicable to finished appliances.

9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

<sup>F321</sup>ANNEX VI

**CORRELATION TABLE**

**Textual Amendments**

**F321** Annex 6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(49)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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*Status: Point in time view as at 31/12/2022.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council. (See end of Document for details)*

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- (1) [OJ C 458, 19.12.2014, p. 25.](#)
- (2) Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.
- (3) Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels ([OJ L 330, 16.12.2009, p. 10.](#))
- (4) [OJ C 136, 4.6.1985, p. 1.](#)
- (5) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([OJ L 316, 14.11.2012, p. 12.](#))
- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82.](#))
- (7) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30.](#))
- (8) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products ([OJ L 285, 31.10.2009, p. 10.](#))
- (9) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ([OJ L 140, 5.6.2009, p. 16.](#))
- (10) Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings ([OJ L 153, 18.6.2010, p. 13.](#))
- (11) Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC ([OJ L 315, 14.11.2012, p. 1.](#))
- (12) Directive 2009/73/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC ([OJ L 211, 14.8.2009, p. 94.](#))
- (13) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13.](#))
- (14) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ([OJ L 338, 13.11.2004, p. 4.](#))
- (15) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC ([OJ L 88, 4.4.2011, p. 5.](#))
- (16) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ([OJ L 330, 5.12.1998, p. 32.](#))
- (17) It is optional for the manufacturer to assign a number to the declaration of conformity.

**Status:**

Point in time view as at 31/12/2022.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2016/426 of the European Parliament and of the Council.