

## SCHEDULE 19

Regulation 22

### Amendment of the Pyrotechnic Articles (Safety) Regulations 2015

#### Introduction

1. The Pyrotechnic Articles (Safety) Regulations 2015 are amended in accordance with paragraphs 2 to 43.

#### Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

- (a) omit the definition of “accreditation”;
- (b) omit the definition of “accreditation certificate”;
- (c) after the definition of “aerial wheel” insert—  
““approved body” has the meaning given to it in regulation 43;”;
- (d) omit the definition of “CE marking”;
- (e) omit the definition of “competent national authority”;
- (f) after the definition of “conformity assessment body” insert—  
““declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 9(1)(a) (declaration of conformity and UK marking);  
“designated standard” has the meaning given to it in regulation 2A;”;
- (g) in the definition of the “Directive”, at the end insert “(as it has effect immediately before exit day)”;;
- (h) omit the definition of “EU declaration of conformity”;
- (i) omit the definition of “harmonised standard”;
- (j) for the definition of “importer” substitute—  
““importer” means any person who—
  - (a) is established in the United Kingdom; and
  - (b) places a pyrotechnic article from a country outside the United Kingdom on the market;”;
- (k) in the definition of “make available on the market” for “EU” substitute “United Kingdom”;
- (l) omit the definition of “national accreditation body”;
- (m) omit the definition of “notified body requirements”;
- (n) in the definition of “place on the market” for “EU” substitute “United Kingdom”;
- (o) omit the definition of “registration number”;
- (p) after the definition of “theatrical pyrotechnic article” insert—  
““UK marking” means the marking in the form published in accordance with Article 30(1) of RAMS;  
“UK registration number” means the number assigned to a pyrotechnic article by an approved body under paragraph 5(a) of Schedule 6 (operational obligations of approved bodies);

“UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;”.

(3) After paragraph (1) insert—

“(1A) Schedules 2A and 3A reproduce the provisions of Annexes II and III (respectively) to the Directive with amendments to correct deficiencies in retained EU law.

(1B) A reference to a provision of Schedule 2A and 3A is a reference to the equivalent provision of the Annex to the Directive as set out in that Schedule.”.

(4) Omit paragraph (3).

### **Insertion of regulation 2A**

3. After regulation 2 insert—

#### **“Interpretation: designated standard**

**2A.**—(1) Subject to paragraphs (6) and (7), in these Regulations a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation 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), a “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 regulation 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).

(4) When considering whether the 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 persons 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 technical specifications adopted by the other recognised standardisation bodies.

(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 regulation, a reference to a “product” is a reference to a pyrotechnic article to which these Regulations apply.

(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) are made by statutory instrument.

(11) A statutory instrument containing regulations made under paragraph (9) is subject to annulment in pursuance of a resolution of either House of Parliament.”

#### **Amendment to regulation 6**

4. In regulation 6 (categorisation), in paragraph (b) for “a notified body” substitute “an approved body”.

#### **Amendment to regulation 8**

5. In regulation 8 (technical documentation and conformity assessment), in paragraph (b) for “Annex II to the Directive (as amended from time to time)”, in each place it occurs, substitute “Schedule 2A”.

#### **Amendment to regulation 9**

6.—(1) Regulation 9 (EU declaration of conformity and CE marking) is amended as follows.

(2) In the heading—

- (a) omit “EU”; and
- (b) for “CE” substitute “UK”.

(3) In paragraph (1)(a) omit “(EU declaration of conformity)”.

(4) In paragraph (1)(b)—

- (a) for “CE” where it first appears substitute “UK”;
- (b) omit “(CE marking)”.

(5) In paragraph (2) omit “EU”.

(6) For paragraph (3) substitute—

“(3) Where a pyrotechnic article is subject to more than one enactment requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which identifies each enactment by its title.”.

#### **Amendment to regulation 10**

7. In regulation 10 (retention of technical documentation and EU declaration of conformity) and in the heading to that regulation, omit “EU”.

#### **Amendment to regulation 11**

8. In regulation 11 (labelling of pyrotechnic articles other than pyrotechnic articles for vehicles)

- (a) for paragraph (1)(c) substitute—
  - “(c) in English.”; and
- (b) omit paragraphs (3) to (5).

#### **Amendment to regulation 12**

- 9. In regulation 12 (labelling of pyrotechnic articles for vehicles)—
  - (a) in paragraph (1)(c), before “registration number”, insert “UK”; and
  - (b) in paragraphs (3) and (4), before “safety data sheet”, insert “UK”.

#### **Amendment to regulation 13**

- 10. In regulation 13 (compliance procedures for series production), in paragraph (2)(b)—
  - (a) for “harmonised” substitute “designated”; and
  - (b) omit “EU”.

#### **Amendment to regulation 15**

- 11. In regulation 15 (requirements which must be satisfied before an importer places a pyrotechnic article on the market)—
  - (a) in paragraph (1)(c)(i) for “CE” substitute “UK”; and
  - (b) in paragraph (2)(b), before “safety data sheet”, insert “UK”.

#### **Amendment to regulation 17**

- 12. In regulation 17 (information identifying importer)—
  - (a) in paragraph (2)—
    - (i) for “competent national authority” substitute “enforcing authority”;
    - (ii) omit “in the member State in which it is to be made available to end users”;
  - (b) for paragraph (3) substitute—
    - “(3) Paragraph (1) does not apply where—
      - (a) either—
        - (i) it is not possible to set out the information referred to in paragraph (1) on the pyrotechnic article; or
        - (ii) the importer has imported the pyrotechnic article from an EEA state and places it on the market within the period of 18 months beginning with exit day; and
      - (b) before placing the pyrotechnic article on the market, the importer sets out the information referred to in paragraph (1)—
        - (i) on the packaging; or
        - (ii) in a document accompanying the pyrotechnic article.”.

#### **Amendment to regulation 18**

- 13. In Regulation 18 (instructions and safety information)—
  - (a) in paragraph (1) for the words from “in a language” to the word “end-users” in the second place it occurs, substitute “that are clear, legible and in easily understandable English”; and

- (b) omit paragraph (2).

#### **Amendment to regulation 19**

14. In regulation 19 (retention of technical documentation and EU declaration of conformity) omit “EU” from the heading and from paragraph (a).

#### **Amendment to regulation 20**

15. In regulation 20 (traceability), before “registration number”, in both places it occurs, insert “UK”.

#### **Amendment to regulation 22**

16. In regulation 22 (duty to take action in respect of pyrotechnic articles placed on the market which are considered not to be in conformity), in paragraph (2) omit the words from “and” to “market”.

#### **Amendment to regulation 25**

17. In Regulation 25 (requirements which must be satisfied before a distributor makes a pyrotechnic article available on the market)—

- (a) in paragraph (1)(a)—
  - (i) in sub-paragraph (i) for “CE” substitute “UK”; and
  - (ii) in sub-paragraph (iii) for the words from “in a language” to the words “on the market”, substitute “that are clear, legible and in easily understandable English”; and
- (b) in paragraph (2)(c), before “safety data sheet”, insert “UK”.

#### **Amendment to regulation 27**

18. In regulation 27 (duty to take action in respect of pyrotechnic articles made available on the market which are not in conformity), in paragraph (2) omit the words from “and” to “market”.

#### **Amendment to regulation 35**

19. In Regulation 35 (supply of safety data sheet)—

- (a) in the heading and in the body of the text, before “safety data sheet”, insert “UK”; and
- (b) omit paragraph (a).

#### **Revocation of regulation 36**

20. Omit regulation 36 (translation of declaration of conformity).

#### **Amendment to regulation 38**

21. In Regulation 38 (prohibition on improper use of CE marking)—

- (a) in the heading for “CE” substitute “UK”;
- (b) in paragraphs (1) and (2) for “the CE” substitute “a UK”; and
- (c) in paragraphs (3) and (4) for “CE” substitute “UK”.

## Insertion of regulations 38A to D

22. After regulation 38 insert—

### “Obligations which are met by complying with obligations in the Directive

**38A.**—(1) In this regulation—

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex to the Directive; and
- (b) “CE marking” has the meaning given to it in Article 3(22); and
- (c) “harmonised standard” has the meaning given to it in Article 3(14).

(2) Paragraph (3) applies where, before placing a pyrotechnic article on the market, the manufacturer—

- (a) ensures that the pyrotechnic article has been designed and manufactured in accordance with the essential safety requirements set out in Annex I;
- (b) ensures that the technical documentation referred to in Annex II has been drawn up;
- (c) ensures that the conformity assessment procedure that applies to that pyrotechnic article in accordance with Article 17 has been carried out;
- (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
- (e) affixes a CE marking and other markings, in accordance with Articles 19 and 20(1) to (4);
- (f) draws up an EU declaration of conformity, in accordance with Article 18; and
- (g) ensures that the EU declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

- (a) the requirements of regulation 7, 8, 9(1) and 9(3) are to be treated as being satisfied;
- (b) regulations 2(2)(a), 9(2), 10, 13(2) and 38 apply subject to the modifications in paragraph (8);
- (c) Part 3 does not apply; and
- (d) regulations 60(1)(a), (c), (d) and (f) do not apply.

(4) Paragraph (5) applies where, before placing a pyrotechnic article on the market, the importer ensures that—

- (a) the conformity assessment procedure that applies to that pyrotechnic article in accordance with Article 17 has been carried out;
- (b) the manufacturer has drawn up the technical documentation referred to in Annex II; and
- (c) the vessel bears the CE marking and other markings referred to in Article 20(3) to (4).

(5) Where this paragraph applies—

- (a) the requirements of regulation 15(a) to (c) are to be treated as being satisfied; and
- (b) regulations 2(2)(a), 16(1) and 19, and regulation 29 insofar as it relates to importers, apply subject to the modifications in paragraph (8).

(6) Paragraph (7) applies where, before making a pyrotechnic article available on the market, a distributor ensures that the vessel bears the CE marking.

(7) Where this paragraph applies—

- (a) regulation 25(1)(a)(i) is to be treated as being satisfied; and
- (b) regulations 2(2)(a), 26(1), and regulation 29 insofar as it relates to distributors, apply subject to the modifications in paragraph (8).

(8) The modifications referred to in paragraphs (3)(b), (5)(b) and (9)(b) are that—

- (a) any reference to “declaration of conformity” is to be read as a reference to the EU declaration of conformity;
- (b) any reference to “UK marking” is to be read as a reference to the CE marking;
- (c) any reference to “essential safety requirements” is to be read as a reference to the essential safety requirements referred to in Annex I;
- (d) any reference to “designated standard” is to be read as a reference to a harmonised standard;
- (e) any reference to “relevant conformity assessment procedure” is to be read as a reference to the conformity assessment procedure that applies to the pyrotechnic article in accordance with Article 17;
- (f) any reference to “technical documentation” is a reference to the technical documentation referred to in Annex II.

#### **Obligations which are met by complying with obligations in the Directive that relate to the registration number**

**38B.**—(1) In this regulation—

- (a) any reference to an Article is a reference to an Article of the Directive; and
- (b) “registration number” means a number comprising the elements set out in Article 1 of Commission Implementing [Directive 2014/58/EU](#) of 16 April 2014 setting up a system for the traceability of pyrotechnic articles, as it has effect immediately before exit day<sup>(1)</sup>.

(2) Paragraph (3) applies where, before placing a pyrotechnic article on the market, the manufacturer labels the pyrotechnic article with a registration number in accordance with Article 10(2) or Article 11(1), as applicable.

(3) Where this paragraph applies—

- (a) the requirements of regulations 11, 12 and 20 apply subject to the modifications in paragraph (8); and
- (b) regulation 60(1)(f) does not apply.

(4) Paragraph (5) applies where, before placing a pyrotechnic article on the market, the importer ensures that the pyrotechnic article has been labelled with a registration number in accordance with Articles 10(2) or 11(1), as applicable.

(5) Where this paragraph applies the requirements of regulation 15(1)(d) and 20 apply subject to the modifications at paragraph (8).

(6) Paragraph (7) applies where, before making a pyrotechnic article available on the market, a distributor verifies that the pyrotechnic article has been labelled with a registration number in accordance with Articles 10(2) or 11(1), as applicable.

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(1) OJ No. L 178, 28.06.2013, p.27.

(7) Where this paragraph applies the requirements of regulation 25(1)(b) apply subject to the modifications at paragraph (8).

(8) The modifications referred to in paragraphs (3)(a), (5) and (7) are that—

- (a) any reference to “Schedule 3” in regulations 11 or 12 is to be read as a reference to Schedule 3 subject to the modification that, in paragraph 1(d) of that Schedule, the reference to “UK registration number” is to be read as a reference to the registration number; and
- (b) any reference to “UK registration number” is to be read as a reference to the registration number.

### **Obligations which are met by complying with obligations in the Directive that relate to safety data sheet**

**38C.**—(1) In this regulation “safety data sheet” means a document—

(a) compiled in accordance with Annex II to Regulation No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency<sup>(2)</sup>, as it has effect in EU law immediately before exit day; and

(b) which takes into account the specific needs of professional users.

(2) Paragraph (3) applies where, before placing a pyrotechnic article for vehicles on the market, the manufacturer draws up a safety data sheet in English.

(3) Where this paragraph applies—

- (a) regulation 12 applies subject to the modification—
  - (i) in paragraph (10); and
  - (ii) that paragraph (4) of that regulation is omitted; and
- (b) regulation 60(1)(f) does not apply.

(4) Paragraph (5) applies where, before placing a pyrotechnic article for vehicles on the market, the importer ensures that the article is accompanied by a safety data sheet in English.

(5) Where this paragraph applies regulation 15 applies subject to the modification that paragraph (2) of that regulation is substituted by the following—

“(2) In paragraph (1)(c)(ii), “required documents” means—

- (a) the documents that are required to be provided with the pyrotechnic article pursuant to regulation 11(6); and
- (b) the safety data sheet.”.

(6) Paragraph (7) applies where, before making a pyrotechnic article for vehicles available on the market, a distributor verifies that the article is accompanied by a safety data sheet in English.

(7) Where this paragraph applies regulation 25 applies subject to the modification that paragraph (2) of that regulation is substituted by the following—

“(2) In paragraph (1)(a)(ii), “required documents” means—

- (a) the documents that are required to be provided with the pyrotechnic article pursuant to regulations 11(6) and 17(3)(b); and
- (b) the safety data sheet.”.

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(2) OJ L 396, 30.12.2006, p. 1.



(8) Paragraph (9) applies where, before making a pyrotechnic article for vehicles available on the market to a professional user, an economic operator supplies to the professional user a safety data sheet in respect of that article.

(9) Where this paragraph applies regulation 35 applies subject to the modification at paragraph (10).

(10) The modification referred to in sub-paragraphs (3) and (9) is that any reference to a “UK safety data sheet” is to be read as a reference to a safety data sheet.

### **Conformity assessment procedure obligation which is met by complying with the Directive**

**38D.**—(1) In this regulation any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive.

(2) Paragraph (3) applies where, prior to the manufacture of a pyrotechnic article, the manufacturer ensures that the conformity assessment procedure that applies to that pyrotechnic article in accordance with Article 17(a), referred to as Module B and set out in Annex II, has been carried out.

(3) Where this paragraph applies—

- (a) the requirement in regulation 40(a) to conform to Module B as set out in Annex II is to be treated as being satisfied;
- (b) any reference to “relevant conformity assessment procedure” in regulations 8(a), 9(1), 15(1)(a), 38(1)(b) and 41(b) is to be read as including the conformity assessment procedure referred to in Article 17(1)(a), referred to as Module B and set out in Annex II; and
- (c) any reference to “technical documentation” in regulations 8(b), 10, 15(1)(b) and 19(b) is to be read as including the technical documentation relating to the design of the pyrotechnic article referred to in Module B of Annex II. ”.

### **Amendment to regulation 39**

**23.** In regulation 39 (presumption of conformity), in paragraph (1)—

- (a) for “harmonised” substitute “designated”; and
- (b) omit the words from “the reference” to “Union”.

### **Amendment to regulation 40**

**24.** In Regulation 40 (conformity assessment procedures)—

- (a) for “Annex II to the Directive (as amended from time to time)” substitute “Schedule 2A”;
- (b) in paragraph (a) for “EU-type” substitute “Type”; and
- (c) for “a notified body”, in each place it occurs, substitute “an approved body”.

### **Amendment to regulation 41**

**25.** In Regulation 41 (EU declaration of conformity)—

- (a) omit “EU” from the heading and from the body of the text;
- (b) for “Annex II to the Directive (as amended from time to time)” substitute “Schedule 2A”;
- and
- (c) for “Annex III to the Directive (as amended from time to time)” substitute “Schedule 3A”.

#### **Amendment to regulation 42**

26. In Regulation 42 (CE Marking)—

- (a) for “CE”, in each place it occurs (including the heading), substitute “UK”; and
- (b) for “notified body”, in each place it occurs, substitute “approved”.

#### **Amendment to Part 4**

27. For Part 4 (notification of conformity assessment bodies), substitute—

### **“PART 4**

#### **Approval of Conformity Assessment Bodies**

##### **Approved bodies**

43.—(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 regulation 44 (approval of conformity assessment bodies); or
- (b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 49(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body’s status as a notified body.

(2) Paragraph (1) has effect subject to regulation 47 (restriction, suspension or withdrawal of approval).

(3) In this Part—

“notified body” means a body—

- (a) which the Secretary of State had before exit day notified to the European Commission and the member States, in accordance with Article 21 of the Directive; and
- (b) in respect of which no objections had been raised, as referred to in regulation 43(1)(b); and

“approved body requirements” means the requirements set out in Schedule 5.

##### **Approval of conformity assessment bodies**

44.—(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—

(a) a description of—

- (i) the conformity assessment activities that the conformity assessment body intends to carry out;
- (ii) the relevant conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

- (iii) the pyrotechnic article 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), 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 regulation “accreditation certificate” means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

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

- 45.**—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).
- (2) The presumption in paragraph (1) is rebuttable.

### **Monitoring**

- 46.** The Secretary of State must monitor each approved body with a view to verifying that the body—
- (a) continues to meet the approved body requirements;
  - (b) meets any conditions set—
    - (i) in accordance with regulation 44(6)(b); or
    - (ii) in the case of an approved body which was a notified body immediately before exit day, in accordance with regulation 44(6)(b) as it applied immediately before exit day; and
  - (c) carries out its functions in accordance with these Regulations.

### **Restriction, suspension or withdrawal of approval**

- 47.**—(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 regulation 46(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 43.

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 46(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 43.

(3) In deciding what action is required 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—

- (a) on the request of the Secretary of State, transfer its files (including the register which it maintains under paragraph 5 of Schedule 6 (operational obligations of approved bodies)) to another approved body or to the Secretary of State; or
- (b) in the absence of a request under sub-paragraph (a), ensure that its files are kept available for the Secretary of State and each enforcing authority for a period equal to that specified in paragraphs 5 and 6 of Schedule 6.

(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.

### **Operational matters in relation to approved bodies**

**48.**—(1) Subject to the terms of its appointment and to paragraph (3), an approved body must carry out the conformity assessment activities and procedures—

- (a) in respect of which the body's approval was given under regulation 44; or
- (b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

- (a) to issue a Type-examination certificate referred to in Schedule 2A; or
- (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 42(4).

### **Subsidiaries and contractors**

**49.**—(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—
- (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 regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006<sup>(3)</sup>.

#### **Register of approved bodies**

- 50.**—(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.
- (2) The register referred to in paragraph (1) must be made publicly available.

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

- 51.** 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 regulation 46; and
  - (c) compiling and maintaining the register of approved bodies, in accordance with regulation 50.”.

#### **Amendment to regulation 55**

- 28.** In regulation 55 (exercise of enforcement powers), omit paragraph (c).

#### **Amendment to regulation 57**

- 29.** In Regulation 57 (enforcement action in respect of pyrotechnic articles which are not in conformity and which present a risk)—
- (a) in paragraph (2), for “notified” substitute “approved”;

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(3) 2006 c.46.

- (b) omit paragraphs (4) and (7); and
- (c) in paragraph (8)—
  - (i) for “notices in paragraphs (6) and (7)” substitute “notice in paragraph (6)”; and
  - (ii) in sub-paragraph (f)(ii) for “harmonised” substitute “designated”.

**Amendment to regulation 58**

- 30.** Omit regulation 58 (EU safeguard procedure).

**Amendment to regulation 59**

**31.** In regulation 59 (enforcement action in respect of pyrotechnic articles which are in conformity, but present a risk)—

- (a) omit paragraph (3); and
- (b) in paragraph (4) for “notices referred to in paragraphs (2) and (3)” substitute “notice referred to in paragraph (2)”.

**Amendment to regulation 60**

**32.** In Regulation 60 (enforcement action in respect of formal non-compliance)—

- (a) in paragraph (1)(a) for “CE”, in each place it occurs, substitute “UK”;
- (b) in paragraph (1)(b)—
  - (i) for “a notified body” substitute “an approved body”; and
  - (ii) for “the notified body” substitute “the approved body”; and
- (c) in paragraph (1)(c)—
  - (i) omit “EU”, in each place it occurs; and
  - (ii) for “CE” substitute “UK”.

**Amendment to regulation 61**

**33.** In regulation 61 (restrictive measures) omit “(as amended from time to time)”.

**Amendment to regulation 62**

**34.** In Regulation 62 (offences)—

- (a) in paragraph (1)—
  - (i) in sub-paragraphs (d) and (t) for “CE marking” substitute “UK marking”;
  - (ii) in sub-paragraphs (d), (e) and (r) omit “EU”; and
  - (iii) in sub-paragraph (q), before “safety data sheet”, insert “UK”;
- (b) in paragraph (2)(f) omit “EU”; and
- (c) in paragraph (6) omit “(as amended from time to time)”, in both places it occurs.

**Amendment to regulation 74**

**35.** In Regulation 74 (transitional provisions) in paragraph (5), for “another” substitute “a”.

## Insertion of Transitional provision in relation to EU Exit

36. After regulation 74 (transitional provisions) insert—

### “Transitional provision in relation to EU Exit

74A.—(1) In this regulation—

“pre-exit period” means the period beginning with the commencement date and ending immediately before exit day; and

“product” means a pyrotechnic article to which these Regulations apply.

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 19 to the Product Safety and Metrology (Amendment etc.) (EU Exit) Regulations 2019<sup>(4)</sup> any obligation to which a person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product.

(3) Paragraph (2) does not apply to—

- (a) any obligation of any enforcing authority to inform the European Commission or the member state of any matter;
- (b) any obligation to take action outside the market in respect of that product.

(4) Where during the pre-exit period—

- (a) a product has not been placed on the market; and
- (b) a manufacturer has taken any action under regulation 40 as it had effect immediately before exit day in relation to that product,

that action has effect as if it had been done under regulation 40 as it had effect on and after exit day.”

## Amendment to regulation 75

37.—(1) Regulation 75 (Consequential revocations, savings and amendments) is amended as follows.

(2) In paragraph 2 for “The” substitute “Subject to the modifications made to the 2010 Regulations in paragraph (2A), the”.

(3) After paragraph (2) insert—

“(2A) The modifications referred to in paragraph (2) are as follows—

- (a) in regulations 18(3) and 36(3), for “EU” substitute “UK”;
- (b) in regulation 13, omit paragraph (4);
- (c) in regulation 19—

- (i) omit paragraphs (9) and (11); and
- (ii) for paragraph (10) substitute—

“(10) Where the Secretary of State has sufficient reason to believe that a category 1,2 or 3 firework presents a serious risk to the health or safety of persons in the UK, the Secretary of State shall perform an appropriate evaluation.”

- (d) in regulation 30 omit paragraph (4);
- (e) in regulation 37—

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(4) S.I. 2019/xxxx.

*Draft Legislation: This is a draft item of legislation and has not yet been made as a UK Statutory Instrument. This draft has been replaced by a new draft, The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 ISBN 978-0-11-118040-2*

- (i) omit paragraphs (10) and (12); and
- (ii) for paragraph (11) substitute—

“(11) Where the Secretary of State has sufficient reason to believe that a pyrotechnic article presents a serious risk to the health or safety of persons in the UK, the Secretary of State shall perform an appropriate evaluation.””

### **Amendment to Schedule 2**

**38.** In Schedule 2 (essential safety requirements) in paragraph 1(1) for “notified” substitute “approved”.

### **Insertion of Schedule 2A**

**39.** After Schedule 2 insert—

“SCHEDULE 2A Regulations 2(3), 8, 40(a), 41(b),  
48(3)(a)

Conformity Assessment Procedures (Annex II to the Directive)

## **PART 1**

### **Module B: Type Examination**

**1.** Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a pyrotechnic article and verifies and attests that the technical design of the pyrotechnic article meets the requirements of these Regulations that apply to it.

**2.** Type examination shall be carried out as an assessment of the adequacy of the technical design of the pyrotechnic article through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).

**3.** The manufacturer shall lodge an application for a Type examination with a single approved body of his choice.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the pyrotechnic article’s conformity with the applicable requirements of these Regulations 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 pyrotechnic article. The technical documentation shall contain, wherever applicable, at least the following elements:
  - (i) a general description of the pyrotechnic article;
  - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;



- (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
- (iv) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations including a list of other relevant technical specifications applied. In the case of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (d) the specimens representative of the production envisaged. The approved body may request further specimens if 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 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.

**4. The approved body shall:**

For the pyrotechnic article:

**4.1.** Examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pyrotechnic article.

For the specimen(s):

**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 designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

**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 designated standards, these have been applied correctly;

**4.4.** Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer, including those in other relevant technical specifications applied, meet the corresponding essential safety requirements of these Regulations;

**4.5.** Agree with the manufacturer on a location where the examinations and tests will be carried out.

**5.** The approved body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

**6.** Where the type meets the requirements of these Regulations that apply to the pyrotechnic article concerned, the approved body shall issue a Type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The Type examination certificate may have one or more annexes attached.

The Type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pyrotechnic articles with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The 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 these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the pyrotechnic article with the essential safety requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination certificate.

8. Each approved body shall inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Secretary of State and other approved bodies may, on request, obtain a copy of the Type examination certificates and/or additions thereto. On request the Secretary of State may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body. The approved body shall keep a copy of the 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.

9. The manufacturer shall keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

## PART 2

### Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals

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, 3 and 4, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

#### 2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic articles with the type described

in the Type examination certificate and with the requirements of these Regulations that apply to them.

### 3. Product checks

An approved body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the pyrotechnic article, taking into account, inter alia, the technological complexity of the pyrotechnic articles and the quantity of production. An adequate sample of the final products, taken on site by the approved body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the pyrotechnic article with the type described in the Type examination certificate and with the relevant requirements of these Regulations. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

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

The manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

### 4. UK marking and declaration of conformity

**4.1.** The manufacturer shall affix the UK marking to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

**4.2.** The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

## PART 3

### Module D: Conformity to type based on quality assurance of the production process

**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 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

### 2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

### 3. Quality system

**3.1.** The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the pyrotechnic article category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the Type examination certificate.

**3.2.** The quality system shall ensure that the pyrotechnic articles are in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations that apply to them.

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.; and
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

**3.3.** The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

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 designated standard.

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 these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article 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.

**3.4.** 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.

**3.5.** The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 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. Surveillance under the responsibility of the approved body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (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.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the 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 approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### 5. UK marking and declaration of conformity

5.1. The manufacturer shall affix the UK marking, and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 3.1;
- (b) the information relating to the change referred to in point 3.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other 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.

## PART 4

### Module E: Conformity to type based on product quality assurance

**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 in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

#### **2.** Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### **3.** Quality system

**3.1.** The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include the following information:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the pyrotechnic article category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the Type examination certificate.

**3.2.** The quality system shall ensure compliance of the pyrotechnic articles with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

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.

**3.3.** The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

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 designated standard.

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 these Regulations.

The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e), in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article 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.

**3.4.** 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.

**3.5.** The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 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. Surveillance under the responsibility of the approved body**

**4.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

**4.2.** The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (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.

**4.3.** The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

**4.4.** In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the 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 approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **5. UK marking and declaration of conformity**

**5.1.** The manufacturer shall affix the UK marking, and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

**5.2.** The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

**6.** The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 3.1;
- (b) the information relating to the change referred to in point 3.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

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

## PART 5

### Module G: Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pyrotechnic article concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of these Regulations that apply to it.

#### 2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the approved body referred to in point 4. The documentation shall make it possible to assess the pyrotechnic article's conformity with the relevant requirements, 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 pyrotechnic article. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the pyrotechnic article;
- (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 pyrotechnic article;
- (d) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the case of partly applied designated 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.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pyrotechnic article has been placed on the market.

#### 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic article with the applicable requirements of these Regulations.

#### 4. Verification



An approved body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the pyrotechnic article with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

The 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 pyrotechnic article, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

#### 5. UK marking and declaration of conformity

**5.1.** The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in point 4, the latter's identification number to each pyrotechnic article that satisfies the applicable requirements of these Regulations.

**5.2.** The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

## PART 6

### Module H: Conformity based on full quality assurance

**1.** Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned satisfy the requirements of these Regulations that apply to them.

#### 2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### 3. Quality system

**3.1.** The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) the technical documentation for one model of each pyrotechnic article category intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
  - a general description of the pyrotechnic article;
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
- a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports;
  - (c) the documentation concerning the quality system;
  - (d) a written declaration that the same application has not been lodged with any other approved body.

**3.2.** The quality system shall ensure compliance of the pyrotechnic articles with the applicable requirements of these Regulations.

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. That 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 design and product quality;
- (b) the technical design specifications, including standards that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of these Regulations will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pyrotechnic articles pertaining to the pyrotechnic article category covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

**3.3.** The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

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 designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The manufacturer shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

**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.

**3.5.** The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 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. Surveillance under the responsibility of the approved body**

**4.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

**4.2.** The manufacturer shall, for assessment purposes, allow the approved body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;
- (b) the quality records as provided for by the design part of the quality system such as the results of analyses, calculations, tests, etc.;
- (c) the quality records as provided for by the manufacturing part of the quality system such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

**4.3.** The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

**4.4.** In addition, the approved body may pay unexpected visits to the manufacturer. During such visits, the approved body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **5. UK marking and declaration of conformity**

**5.1.** The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that satisfies the applicable requirements of these Regulations.

**5.2.** The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

**6.** The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the technical documentation referred to in point 3.1;
- (b) the documentation concerning the quality system referred to in point 3.1;

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- (c) the information relating to the change referred to in point 3.5, as approved;
- (d) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

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

### **Amendment to Schedule 3**

40. In Schedule 3, in paragraph 1(d), before “registration number” insert “UK”.

### **Insertion of Schedule 3A**

41. After Schedule 3 insert—

“SCHEDULE 3A

Regulations 2(3), 41(c)

#### Declaration of Conformity (Annex III to the Directive)

- 1) UK registration number:
- 2) Product, batch or serial number:
- 3) Name and address of the manufacturer:
- 4) This declaration of conformity is issued under the sole responsibility of the manufacturer.
- 5) Object of the declaration (identification of product allowing traceability):
- 6) The object of the declaration described above is in conformity with the relevant statutory requirements:
- 7) References to the designated standards used or references to the other technical specifications in relation to which conformity is declared:
- 8) The approved body (name, number) performed (description of intervention) and issued the certificate:
- 9) Additional information:

Signed for and on behalf of:

[place and date of issue]:

[name, function] [signature]:”.

### **Amendment to Schedule 5**

42. In Schedule 5—

- (a) in the heading for “Notified” substitute “Approved”;
- (b) in paragraph 9(b) for “a notified” substitute “an approved”;
- (c) in paragraph 11(c)—
  - (i) for “harmonised” substitute “designated”; and
  - (ii) omit “the Directive and of”;
- (d) in paragraph 17—
  - (i) for “notified” substitute “approved”; and

- (ii) for “under the Directive” substitute “by the Secretary of State”.

### **Amendment to Schedule 6**

**43.**—(1) Schedule 6 is amended as follows.

- (2) In the heading for “notified” substitute “approved”.
- (3) For “a notified body”, in each place it occurs, substitute “an approved body”.
- (4) For “the notified body”, in each place it occurs, substitute “the approved body”.
- (5) In paragraph 5—
- (a) before “registration number”, in both places it occurs, insert “UK”; and
- (b) in sub-paragraph (a), for the words from “Article 1” to “time to time)” substitute “paragraph 5A”;
- (6) After paragraph 5 insert—

“**5A.**—(1) Pyrotechnic articles must be labelled with a UK registration number comprising the following:

- (a) the four-digit identification number of the approved body that has issued a Type-examination certificate (Schedule 2A, Module B), certificate of conformity (Schedule 2A, Module G) or quality system approval (Schedule 2A, Module H), as applicable;
- (b) the category of the pyrotechnic article for which conformity is certified in abbreviated format, in upper case—
- (i) F1, F2, F3 or F4 for fireworks of category 1, 2, 3 and 4 respectively;
- (ii) T1 or T2 for theatrical pyrotechnic articles of category T1 and T2 respectively; and
- (iii) P1 or P2 for other pyrotechnic articles of category P1 and P2 respectively; and
- (c) the processing number used by the approved body for the pyrotechnic article.

(2) The UK registration number must be structured as follows: ‘XXXX — YY — ZZZZ...’, where XXXX refers to sub-paragraph (1)(a), YY refers to sub-paragraph (1)(b) and ZZZZ... refers to sub-paragraph (1)(c).”

- (7) In paragraph 6—
- (a) for “After 16th October 2016” substitute “From exit day”;
- (b) in sub-paragraph (a) for the words from “the Annex” to “time to time)” substitute “paragraph 6A”;
- (c) in sub-paragraph (b) for “notified” substitute “approved”.
- (8) After para 6 insert—

“**6A.**—(1) Entries made in the register from exit day must contain at least the following information:

- (a) UK registration number;
- (b) date of issue of Type-examination certificate (where the conformity assessment procedure set out in Part 1 of Schedule 2A (Module B) has been undertaken), certificate of conformity (where the conformity assessment procedure set out in Part 5 of Schedule 2A (Module G) has been undertaken) or quality system approval (where the conformity assessment procedure set out in Part 6 of

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Schedule 2A (Module H) has been undertaken) as applicable, and date of expiry where applicable;

- (c) manufacturer;
- (d) type of product (generic) and subtype, if applicable;
- (e) where applicable, which conformity assessment procedure has been undertaken from those set out in Part 2 of Schedule 2A (Module C2), Part 3 of Schedule 2A (Module D) and Part 4 of Schedule 2A (Module E); and
- (f) where applicable, the approved body that undertook the conformity assessment procedure described in sub-paragraph (e).

(2) Sub-paragraphs (1)(e) and (1)(f) apply where the register is maintained by an approved body carrying out the conformity assessment procedure set out in Part 1 of Schedule 2A (Module B), except where the relevant information is not known to that approved body.”

(9) In paragraph 7, for “harmonised” substitute “designated”.

(10) In paragraph 14 for “notified under the Directive” substitute “approved under these Regulations”.

(11) In paragraph 15—

- (a) for “notified”, in the second place it occurs, substitute “approved”; and
- (b) omit “under the Directive”.