SCHEDULES

SCHEDULE 3

Regulation 9(b)(i)

Applicable conformity assessment procedures

PART 1

Module B: [F1EU-type][F1Type] Examination

Textual Amendments

F1 Word in Sch. 3 Pt. 1 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 20 para. 36(a)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. [F2Type] examination is the part of a conformity assessment procedure in which [F3an approved] body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in paragraph 1 of Schedule 1.

2. [F4Type] examination must be carried out by an assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in paragraphs 3 and 4 without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or the manufacturer's authorised representative.

3. The manufacturer must lodge an application for [F5Type] examination with a single [F6approved] body of the manufacturer's choice. The application must specify the aspects of the essential requirements for which examination is requested and must include—

(a) the name and address of the manufacturer or, if the application is lodged by an authorised representative, the name and address of the authorised representative and of the manufacturer;

(b) a written declaration that the same application has not been lodged with another [F6approved] body;

(c) the technical documentation.

4. The technical documentation referred to in paragraph 3(c) of this Schedule must make it possible to assess the conformity of the apparatus with the applicable requirements of these Regulations and must include an adequate analysis and assessment of the risks posed by the apparatus. The technical documentation must specify the applicable requirements and cover, as far as is relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation must contain, where applicable, at least the following elements—

(a) a general description of the apparatus;

(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 apparatus;

(d) a list of the **[**F7designated**]** standards applied in full or in part F8... and, where the harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of a partly applied harmonised standard, the technical documentation must specify the parts of the standard that have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

5. The **[**F9approved**]** body must examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.

6. The **[**F10approved**]** body must draw up an evaluation report which records the activities undertaken in accordance with paragraph 5 and their outcomes. Without prejudice to its obligations to the notifying authorities, the **[**F10approved**]** body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

7. Where the type meets the requirements of these Regulations that apply to the apparatus concerned, the **[**F11approved**]** body must issue **[**F12a Type**]** examination certificate to the manufacturer.

8. The **[**F13Type**]** examination certificate, which may be accompanied by one or more annexes, must contain—

(a) the name and address of the manufacturer;

(b) the conclusions of the examination of the apparatus;

(c) the aspects of the essential requirements covered by the examination;

(d) the conditions (if any) for the validity of the certificate; and

(e) the necessary data for the identification of the approved type.

9. The **[**F14Type**]** examination certificate and any annexes to that certificate must contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

10. Where the type does not satisfy the applicable requirements of these Regulations, the **[**F15approved**]** body must refuse to issue the **[**F16Type**]** examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

11. The **[**F17approved**]** body must 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 must determine whether such changes require further investigation. If so, the **[**F17approved**]** body must inform the manufacturer accordingly.

12. The manufacturer must inform the **[**F18approved**]** body that holds the technical documentation relating to the **[**F19Type**]** examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications must require additional approval in the form of an addition to the **[**F19Type**]** examination certificate.

13. Each **[**F20approved**]** body must inform its notifying authority of any **[**F21Type**]** examination certificates or any additions thereto, which it has issued or withdrawn and, must periodically or upon request, make available to its notifying authority a list of such certificates and additions thereto that it has refused, suspended or otherwise restricted.

14. Each **[**F22approved**]** body must inform the other **[**F22approved**]** bodies of any **[**F23Type**]** examination certificates or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted. Upon request from another **[**F22approved**]** body, **[**F24an approved**]** body must inform the requesting body of the **[**F23Type**]** examination certificates that it has issued.

15. **[**F25The Secretary of State**]** and the other **[**F26approved**]** bodies may, on request, obtain a copy of the **[**F27Type**]** examination certificate and any additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examination carried out by the **[**F26approved**]** body. The **[**F26approved**]** body must keep a copy of the **[**F27Type**]** 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.

16. The manufacturer must keep a copy of the **[**F28Type**]** examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

17. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 12 and 16 of this Schedule, provided that these obligations are specified in the authorised representative's written mandate.

PART 2

Module C: conformity to type based on internal production control

18. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations set out in paragraphs 19 and 20 of this Schedule and ensures and declares that the apparatus concerned is in conformity with the type described in the **[**F29Type**]** Examination certificate and satisfies the requirements of these Regulations that apply to it.

Manufacturing E+W+S

19. The manufacturer must take all measures necessary to ensure that the manufacturing process and the monitoring of that process ensure the conformity of the manufactured apparatus with the approved type described in the **[**F30Type**]** examination certificate and with the requirements of these Regulations that apply to it.

Extent Information

E18 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F30 Word in Sch. 3 para. 19 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 20 para. 37(a)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturing N.I.

19. The manufacturer must take all measures necessary to ensure that the manufacturing process and the monitoring of that process ensure the conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of these Regulations that apply to it.

[F31UK] marking and F32... declaration of conformity E+W+S

20.—(1) The manufacturer must affix the **[**F33UK**]** marking to each individual apparatus that is in conformity with the type described on the **[**F34Type**]** examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written F35... declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The F35... declaration of conformity must identify the apparatus model for which it has been drawn up.

(3) A copy of the F36... declaration of conformity must be made available to the relevant authorities upon request.

Extent Information

E19 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F31 Word in Sch. 3 para. 20 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 20 para. 37(b)(i)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F32 Word in Sch. 3 para. 20 omitted (E.W.S.) (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. 20 para. 37(b)(ii)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F33 Word in Sch. 3 para. 20(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 20 para. 37(c)(i)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F34 Word in Sch. 3 para. 20(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 20 para. 37(c)(ii)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F35 Word in Sch. 3 para. 20(2) omitted (E.W.S.) (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. 20 para. 37(d)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F36 Word in Sch. 3 para. 20(3) omitted (E.W.S.) (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. 20 para. 37(d)** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

CE marking and EU declaration of conformity N.I.

20.—(1) The manufacturer must affix the CE marking to each individual apparatus that is in conformity with the type described on the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been

placed on the market. The EU declaration of conformity must identify the apparatus model for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

Authorised representative

21. The manufacturer's obligations set out in paragraph 20 of this Schedule may be fulfilled by an authorised representative on behalf of the manufacturer and under the responsibility of the manufacturer provided that these responsibilities are set out in the authorised representative's written mandate.

Changes to legislation:
There are currently no known outstanding effects for the The Electromagnetic Compatibility Regulations 2016, SCHEDULE 3.