ANNEX V

[F1]... TYPE-EXAMINATION(Module B)

1. [F2]... Type-examination is the part of a conformity assessment procedure in which **[**[F3]an approved**]** body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the requirements of this Regulation that apply to it.

Textual Amendments

F2 Word in Annex 5 para. 1 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Annex 5 para. 1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2. [F4]... Type-examination shall be carried out by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation, plus examination of a specimen, representative of the production envisaged, of the complete PPE (production type).

Textual Amendments

F4 Word in Annex 5 para. 2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

3. Application for [F5]... type-examination

The manufacturer shall lodge an application for [F6]... type-examination with a single **[**[F7]approved**]** body of his choice.

Textual Amendments

F6 Word in Annex 5 para. 3 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in Annex 5 para. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

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

(b) a written declaration that the same application has not been lodged with any other **[**[F7]approved**]** body;

(c) the technical documentation described in Annex III;

(d) the specimen(s) of the PPE representative of the production envisaged. The **[**F7approved**]** body may request further specimens if needed for carrying out the test programme. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

Textual Amendments

F5 Word in Annex 5 para. 3 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

4. F8... Type-examination

The **[**F9approved**]** body shall:

Textual Amendments

F9 Word in Annex 5 para. 4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

(a) examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III need not be taken into account;

(b) for PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;

(c) for PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy;

(d) 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 **[**F10designated**]** standards as well as the elements which have been designed in accordance with other technical specifications;

(e) 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 **[**F10designated**]** standards, these have been applied correctly;

(f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant **[**F10designated**]** standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

Textual Amendments

F10 Word in Annex 5 para. 4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F8 Word in Annex 5 para. 4 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(a)** (with Sch. 35 para. 3(42)); 2020 c. 1, Sch. 5 para. 1(1)

5. Evaluation report

The **[**F11approved**]** 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 **[**F12Secretary of State**]**, the **[**F11approved**]** body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Textual Amendments

F11 Word in Annex 5 para. 5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in Annex 5 para. 5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

6. F13... Type-examination certificate

6.1. Where the type meets the applicable essential health and safety requirements, the **[**F14approved **]** body shall issue **[**F15a**]** type-examination certificate to the manufacturer.

The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.

Textual Amendments

F14 Word in Annex 5 para. 6.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Word in Annex 5 para. 6.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

6.2. The F16... type-examination certificate shall contain at least the following information:

(a) the name and identification number of the **[**F17approved**]** body;

(b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the latter's name and address;

(c) identification of the PPE covered by the certificate (type number);

(d) a statement that the PPE type complies with the applicable essential health and safety requirements;

(e) where **[**F18designated**]** standards have been fully or partially applied, the references of those standards or parts thereof;

(f) where other technical specifications have been applied, their references;

(g) where applicable, the performance level(s) or protection class of the PPE;

(h) for PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model;

(i) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;

(j) any conditions attached to the issue of the certificate;

(k) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19.

Textual Amendments

F17 Word in Annex 5 para. 6.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in Annex 5 para. 6.2(e) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(j)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F16 Word in Annex 5 para. 6.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

6.3. The F19... type-examination certificate may have one or more annexes attached.

Textual Amendments

F19 Word in Annex 5 para. 6.3 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

6.4. Where the type does not satisfy the applicable essential health and safety requirements, the **[**F20approved**]** body shall refuse to issue **[**F21a**]** type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Textual Amendments

F20 Word in Annex 5 para. 6.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Word in Annex 5 para. 6.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F13 Word in Annex 5 para. 6 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

7. Review of the [F22]... type-examination certificate

7.1. The **[**[F23]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 essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the **[**[F23]approved**]** body shall inform the manufacturer accordingly.

Textual Amendments

F23 Word in Annex 5 para. 7.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

7.2. The manufacturer shall inform the **[**[F24]approved**]** body that holds the technical documentation relating to the [F25]... type-examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original [F25]... type-examination certificate.

Textual Amendments

F24 Word in Annex 5 para. 7.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F25 Word in Annex 5 para. 7.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.

7.4. The manufacturer shall ask the **[**F26approved**]** body to review the F27... type-examination certificate either:

(a) in the case of a modification to the approved type referred to in point 7.2;

(b) in the case of a change in the state of the art referred to in point 7.3;

(c) at the latest, before the date of expiry of the certificate.

In order to allow the **[**F26approved**]** body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the F27... type-examination certificate.

Textual Amendments

F26 Word in Annex 5 para. 7.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Word in Annex 5 para. 7.4 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

7.5. The **[**F28approved**]** body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the **[**F28approved**]** body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the F29... type-examination certificate. The **[**F28approved**]** body shall ensure that the review procedure is finalised before the expiry date of the F29... type-examination certificate.

Textual Amendments

F28 Word in Annex 5 para. 7.5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F29 Word in Annex 5 para. 7.5 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the **[**F30approved**]** body with the following:

(a) his name and address and data identifying the F31... type-examination certificate concerned;

(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant **[**F32designated**]** standards or other technical specifications applied;

(c) confirmation that there has been no change in the state of the art as referred to in point 7.3;

(d) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and

(e) for category III products, where not already available to the **[**F30approved**]** body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII, or on the results of audits of his quality system carried out in accordance with Annex VIII.

Textual Amendments

F31 Word in Annex 5 para. 7.6 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Annex 5 para. 7.6(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(j)**; 2020 c. 1, Sch. 5 para. 1(1)

Where the **[**F30approved**]** body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In such cases, the **[**F30approved**]** body shall renew the F31... type-examination certificate.

The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.

If the **[**F30approved**]** body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

Textual Amendments

F30 Word in Annex 5 para. 7.6 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

7.7. If, following the review, the **[**F33approved**]** body concludes that the F34... type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.

Textual Amendments

F33 Word in Annex 5 para. 7.7 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F34 Word in Annex 5 para. 7.7 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F22 Word in Annex 5 para. 7 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

8. Each **[**F35approved**]** body shall inform **[**F36the Secretary of State**]** concerning the F37... type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to **[**F36the Secretary of State**]** the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Textual Amendments

F35 Word in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F36 Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(k)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F37 Word in Annex 5 para. 8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)** ; 2020 c. 1, Sch. 5 para. 1(1)

Each **[**F35approved**]** body shall inform the other **[**F35approved**]** bodies concerning the F37... 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.

[F38The Secretary of State**]** and the other **[**F35approved**]** bodies may, on request, obtain a copy of the F37... type-examination certificates and/or additions thereto. **[**F39The Secretary of State may on request**]** obtain a copy of the technical documentation and the results of the examinations carried out by the **[**F35approved**]** body.

Textual Amendments

F38 Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(k)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F39 Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(k)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

The **[**F35approved**]** body shall keep a copy of the F37... type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the F40... type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the PPE has been placed on the market.

Textual Amendments

F40 Word in Annex 5 para. 9 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2016/425 of the European Parliament and of the Council, ANNEX V.