
Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX I

ESSENTIAL REQUIREMENTS

PRELIMINARY OBSERVATIONS:

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

1. GENERAL REQUIREMENTS

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

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

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

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

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

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

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

- 1.6.3. The warning notices on the appliance and its packaging shall clearly state the type of gas to be used, the gas supply pressure, the appliance category and any restrictions on use, in particular the restriction whereby the appliance shall be installed only in areas where there is sufficient ventilation so as to ensure that the risks presented by it are minimised.
- 1.7. The instructions for incorporation of the fitting into an appliance or its assembly in order to constitute an appliance and for its adjustment, operation and maintenance shall be provided with the fittings concerned as part of the ^{F1}... declaration of conformity.

Textual Amendments

F1 Word in Annex 1 para. 1.7 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(44\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1))

2. MATERIALS

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

3. DESIGN AND CONSTRUCTION

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

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

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assessment in relation to the safety requirements of [F²the Radio Equipment Regulations 2017] or the safety objectives of [F³the Electrical Equipment (Safety) Regulations 2016] shall be taken into account.

Textual Amendments

- F2** Words in Annex 1 para. 3.1.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Annex 1 para. 3.1.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(b)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.1.8. Appliances shall be so designed and constructed as to obviate any gas-related risks due to hazards originating from electromagnetic phenomena. As far as relevant, the results of the conformity assessment in relation to the electromagnetic compatibility requirements of [F⁴the Radio Equipment Regulations 2017] or [F⁵the Electromagnetic Compatibility Regulations 2016] shall be taken into account.

Textual Amendments

- F4** Words in Annex 1 para. 3.1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(c)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Annex 1 para. 3.1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(44)(c)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

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

3.3. Ignition

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

3.4. Combustion

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

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

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

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

3.5. Rational use of energy

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

3.6. Temperature

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

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

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

3.7. Contact with food and water intended for human consumption

Without prejudice to Regulations (EC) No 1935/2004⁽¹⁾ and (EU) No 305/2011⁽²⁾ of the European Parliament and of the Council, materials and parts used in the construction of an appliance which may come into contact with food or water intended for human consumption

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as defined in Article 2 of Council Directive 98/83/EC⁽³⁾, shall not impair quality of the food or water.

ANNEX II

**CONTENT^{F6} ... OF THE GAS SUPPLY CONDITIONS
[^{F7}TO BE PUBLISHED UNDER ARTICLE 4]**

Textual Amendments

- F6** Words in Annex 2 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Annex 2 heading inserted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. [^{F8}The Secretary of State must provide the following content in the information that is published under Article 4]:

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

That communication shall also include either of the following:

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

Textual Amendments

F8 Words in Annex 2 para. 1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(45)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

ANNEX III

CONFORMITY ASSESSMENT PROCEDURES FOR APPLIANCES AND FITTINGS

1. MODULE B: ^{F9}... TYPE-EXAMINATION — PRODUCTION TYPE
- 1.1. ^{F10}... type-examination is the part of a conformity assessment procedure in which [^{F11}an approved] body examines the technical design of an appliance or a fitting and verifies and attests that the technical design of the appliance or the fitting meets the requirements of this Regulation that apply to it.

Textual Amendments

F10 Word in Annex 3 para. 1.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Annex 3 para. 1.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(b)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- 1.2. ^{F12}... type-examination shall be carried out by assessment of the adequacy of the technical design of the appliance or the fitting through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a specimen, representative of the production envisaged, of the complete appliance or fitting (production type).

Textual Amendments

F12 Word in Annex 3 para. 1.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3. The manufacturer shall lodge an application for ^{F13}... type-examination with [^{F14}a single approved] body of his choice.

Textual Amendments

F13 Word in Annex 3 para. 1.3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(a\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Annex 3 para. 1.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(c\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3.1. The application shall include the following:
- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
 - (b) a written declaration that the same application has not been lodged with any other [^{F15}approved] body;
 - (c) the technical documentation. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting. The technical documentation shall contain, wherever applicable, at least the following elements:
 - (1) a general description of the appliance or the fitting;
 - (2) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (3) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
 - (4) a list of the [^{F16}designated] standards applied in full or in part ^{F17}... and, where those [^{F16}designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event

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- of partly applied [^{F16}designated] standards, the technical documentation shall specify the parts which have been applied;
- (5) results of design calculations made, examinations carried out, etc.;
 - (6) test reports;
 - (7) instructions for installation and use of the appliance;
 - (8) the ^{F18}... declaration of conformity of the fitting containing the instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance;
- (d) the specimens representative of the production envisaged. The [^{F19}approved] body may request further specimens where needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant [^{F20}designated] standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

Textual Amendments

- F15** Word in Annex 3 para. 1.3.1(b) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F16** Word in Annex 3 para. 1.3.1(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Annex 3 para. 1.3.1(c) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Word in Annex 3 para. 1.3.1(c) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Word in Annex 3 para. 1.3.1(d) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F20** Word in Annex 3 para. 1.3.1(e) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(e)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.3.2. Where appropriate, the manufacturer shall also submit to the [^{F21}approved] body the following documents:

Textual Amendments

- F21** Word in Annex 3 para. 1.3.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- (a) the ^{F22}... type-examination certificate and the ^{F22}... declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance or the fitting;
- (c) any other document making it possible for the [^{F21}approved] body to improve its assessment.

Textual Amendments

F22 Word in Annex 3 para. 1.3.2(a) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.4. The [^{F23}approved] body shall:

Textual Amendments

F23 Word in Annex 3 para. 1.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

For the appliance or the fitting:

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

For the specimen(s):

- 1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant [^{F24}designated] standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant [^{F25}designated] standards, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant [^{F26}designated] standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;
- 1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

Textual Amendments

F24 Word in Annex 3 para. 1.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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- F25** Word in Annex 3 para. 1.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Word in Annex 3 para. 1.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(f)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.5. The ^{F27}approved] body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the ^{F28}Secretary of State], the ^{F27}approved] body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Textual Amendments

- F27** Word in Annex 3 para. 1.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Annex 3 para. 1.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(g)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.6. Where the appliance or the fitting type meets the requirements of this Regulation, the ^{F29}approved] body shall issue ^{F30}a] type-examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning. The certificate may have one or more annexes attached.

Textual Amendments

- F29** Word in Annex 3 para. 1.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F30** Word in Annex 3 para. 1.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(h)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The ^{F31}... type-examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured appliances or fittings with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Textual Amendments

- F31** Word in Annex 3 para. 1.6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

Where the type does not satisfy the applicable requirements of this Regulation, the [F29 approved] body shall refuse to issue [F30 a] type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The [F32 approved] body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Regulation, and shall determine whether such changes require further investigation. If so, the [F32 approved] body shall inform the manufacturer accordingly.

Textual Amendments

F32 Word in Annex 3 para. 1.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall inform the [F32 approved] body that holds the technical documentation relating to the F33... type-examination certificate of all modifications to the approved type that may affect the conformity of the appliance or the fitting with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original F33... type-examination certificate.

Textual Amendments

F33 Word in Annex 3 para. 1.7 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.8. Each [F34 approved] body shall inform [F35 the Secretary of State] concerning the F36... type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to [F35 the Secretary of State] the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Textual Amendments

F34 Word in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F35 Words in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(i)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

F36 Word in Annex 3 para. 1.8 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [F34 approved] body shall inform the other [F34 approved] bodies concerning the F36... type-examination certificates and/or any additions thereto which it has refused, withdrawn,

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

[^{F37}The Secretary of State] and the other [^{F34}approved] bodies may, on request, obtain a copy of the ^{F36}... type-examination certificates and/or additions thereto. On request, the [^{F38}Secretary of State] may obtain a copy of the technical documentation and the results of the examinations carried out by the [^{F34}approved] body. The [^{F34}approved] body shall keep a copy of the ^{F36}... type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

Textual Amendments

- F37** Words in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(i)(ii)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F38** Words in Annex 3 para. 1.8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(i)(ii)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 1.9. The manufacturer shall keep a copy of the ^{F39}... type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the [^{F40}enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

Textual Amendments

- F39** Word in Annex 3 para. 1.9 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in Annex 3 para. 1.9 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(j)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

Textual Amendments

- F9** Word in Annex 3 para. 1 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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concerned are in conformity with the type described in the ^{F41}... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

Textual Amendments

F41 Word in Annex 3 para. 2.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances or fittings with the type described in the ^{F42}... type-examination certificate and with the requirements of this Regulation that apply to them.

Textual Amendments

F42 Word in Annex 3 para. 2.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.3. Product checks

[^{F43}An approved] body, chosen by the manufacturer, shall carry out product checks or have them carried out at intervals of one year or less, in order to verify the quality of the internal checks on the appliance or the fitting, taking into account, inter alia, the technological complexity of the appliances or the fittings and the quantity of production. An adequate sample of the final appliances or fittings taken on site by [^{F44}the approved] body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the [^{F45}designated] standards, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation. Where a sample does not conform to the acceptable quality level, [^{F44}the approved] body shall take appropriate measures.

Textual Amendments

F43 Words in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(l)(i)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F44 Words in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(l)(i)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F45 Word in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(l)(i)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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The manufacturer shall, under the responsibility of the [F⁴⁶approved] body, affix the [F⁴⁶approved] body's identification number during the manufacturing process.

Textual Amendments

F46 Word in Annex 3 para. 2.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(l)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.4. [F⁴⁷UK] marking and F⁴⁸... declaration of conformity

2.4.1. The manufacturer shall affix the [F⁴⁹UK] marking to each individual appliance or fitting that is in conformity with the type described in the F⁵⁰... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

F49 Word in Annex 3 para. 2.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(m)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F50 Word in Annex 3 para. 2.4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.4.2. The manufacturer shall draw up a written F⁵¹... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [F⁵²enforcement authority] for 10 years after the appliance or fitting has been placed on the market. The F⁵¹... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

Textual Amendments

F51 Word in Annex 3 para. 2.4.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in Annex 3 para. 2.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(n)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the F⁵¹... declaration of conformity shall be made available to the [F⁵³enforcement authority] upon request. A copy of the F⁵¹... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

Textual Amendments

F53 Words in Annex 3 para. 2.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(n)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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Textual Amendments

- F47** Word in Annex 3 para. 2.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(m)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F48** Word in Annex 3 para. 2.4 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(k)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

2.5. Authorised representative

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

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

- 3.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2 and 3.5, and ensures and declares on his sole responsibility that the appliances or fittings concerned are in conformity with the type described in the ^{F54}... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

Textual Amendments

- F54** Word in Annex 3 para. 3.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

3.2. Manufacturing

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

3.3. Quality system

- 3.3.1. The manufacturer shall lodge an application for assessment of his quality system with the [^{F55}approved] body of his choice, for the appliances or fittings concerned.

Textual Amendments

- F55** Word in Annex 3 para. 3.3.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

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

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- (b) a written declaration that the same application has not been lodged with any other [^{F55}approved] body;
- (c) all relevant information for the appliance or the fitting approved under module B;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the ^{F56}... type-examination certificate.

Textual Amendments

F56 Word in Annex 3 para. 3.3.1(e) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1))

- 3.3.2. The quality system shall ensure that the appliances or fittings are in conformity with the type described in the ^{F57}... type-examination certificate and comply with the requirements of this Regulation that apply to them.

Textual Amendments

F57 Word in Annex 3 para. 3.3.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1))

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

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

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

- 3.3.3. The [^{F58}approved] body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.3.2.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F58 Word in Annex 3 para. 3.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant [^{F59}designated] standard.

Textual Amendments

F59 Word in Annex 3 para. 3.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(q)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

- 3.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.3.5. The manufacturer shall keep the [^{F60}approved] body that has approved the quality system informed of any intended change to the quality system.

Textual Amendments

F60 Word in Annex 3 para. 3.3.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The [^{F60}approved] body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.3.2 or whether a reassessment is necessary.

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

- 3.4. Surveillance under the responsibility of the [^{F61}approved] body
- 3.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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- 3.4.2. The manufacturer shall, for assessment purposes, allow the [F62 approved] body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

Textual Amendments

F62 Word in Annex 3 para. 3.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

- 3.4.3. The [F63 approved] body shall carry out periodic audits at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

Textual Amendments

F63 Word in Annex 3 para. 3.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.4.4. In addition, the [F64 approved] body may pay unexpected visits to the manufacturer. During such visits the [F64 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 [F64 approved] body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Textual Amendments

F64 Word in Annex 3 para. 3.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F61 Word in Annex 3 para. 3.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.5. [F65 UK] marking and F66... declaration of conformity
- 3.5.1. The manufacturer shall affix the [F67 UK] marking and, under the responsibility of the [F68 approved] body referred to in point 3.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in

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the ^{F69}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

- F67** Word in Annex 3 para. 3.5.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(r)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F68** Word in Annex 3 para. 3.5.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F69** Word in Annex 3 para. 3.5.1 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

3.5.2. The manufacturer shall draw up a written ^{F70}... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [^{F71}enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The ^{F70}... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

Textual Amendments

- F70** Word in Annex 3 para. 3.5.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F71** Words in Annex 3 para. 3.5.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(s)(i)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the ^{F70}... declaration of conformity shall be made available to the [^{F72}enforcement authority] upon request. A copy of the ^{F70}... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

Textual Amendments

- F72** Words in Annex 3 para. 3.5.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(s)(ii)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F65** Word in Annex 3 para. 3.5 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(r)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F66** Word in Annex 3 para. 3.5 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 36 para. 2(46)(o)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- 3.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the [F73 enforcement authority]:

Textual Amendments

F73 Words in Annex 3 para. 3.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(t)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the documentation referred to in point 3.3.1;
- (b) the information relating to the change referred to in point 3.3.5, as approved;
- (c) the decisions and reports of the [F74 approved] body referred to in points 3.3.5, 3.4.3 and 3.4.4.

Textual Amendments

F74 Word in Annex 3 para. 3.6(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 3.7. Each [F75 approved] body shall inform [F76 the Secretary of State] of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to [F76 the Secretary of State] the list of quality systems approvals refused, suspended or otherwise restricted.

Textual Amendments

F75 Word in Annex 3 para. 3.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(p)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in Annex 3 para. 3.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(u)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [F75 approved] body shall inform the other [F75 approved] bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

- 3.8. Authorised representative

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

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

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

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

in points 4.2 and 4.5, and ensures and declares on his sole responsibility that the appliances or fittings concerned are in conformity with the type described in the ^{F77}... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

Textual Amendments

F77 Word in Annex 3 para. 4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(v\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.2. Manufacturing

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

4.3. Quality system

4.3.1. The manufacturer shall lodge an application for assessment of his quality system with the [^{F78}approved] body of his choice, for the appliances or fittings concerned.

Textual Amendments

F78 Word in Annex 3 para. 4.3.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(w\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other [^{F78}approved] body;
- (c) all relevant information for the product category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the ^{F79}... type-examination certificate.

Textual Amendments

F79 Word in Annex 3 para. 4.3.1(e) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 36 para. 2\(46\)\(v\)](#) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.3.2. The quality system shall ensure compliance of the appliances or the fittings with the type described in the ^{F80}... type-examination certificate and with the applicable requirements of this Regulation.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F80 Word in Annex 3 para. 4.3.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

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

4.3.3. The [^{F81}approved] body shall assess the quality system to determine whether it satisfies the requirements referred to in point 4.3.2.

Textual Amendments

F81 Word in Annex 3 para. 4.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant [^{F82}designated] standard.

Textual Amendments

F82 Word in Annex 3 para. 4.3.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(x)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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

- 4.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 4.3.5. The manufacturer shall keep the [F83 approved] body that has approved the quality system informed of any intended change to the quality system.

Textual Amendments

F83 Word in Annex 3 para. 4.3.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The [F83 approved] body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 4.3.2 or whether a reassessment is necessary.

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

- 4.4. Surveillance under the responsibility of the [F84 approved] body
- 4.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.4.2. The manufacturer shall, for assessment purposes, allow the [F85 approved] body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

Textual Amendments

F85 Word in Annex 3 para. 4.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.4.3. The [F86 approved] body shall carry out periodic audits at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

Textual Amendments

F86 Word in Annex 3 para. 4.4.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- 4.4.4. In addition, the [F87 approved] body may pay unexpected visits to the manufacturer. During such visits the [F87 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 [F87 approved] body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Textual Amendments

F87 Word in Annex 3 para. 4.4.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F84 Word in Annex 3 para. 4.4 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 4.5. [F88 UK] marking and F89... declaration of conformity
- 4.5.1. The manufacturer shall affix the [F90 UK] marking and, under the responsibility of the [F91 approved] body referred to in point 4.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in the F92... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

F90 Word in Annex 3 para. 4.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(y)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F91 Word in Annex 3 para. 4.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F92 Word in Annex 3 para. 4.5.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 4.5.2. The manufacturer shall draw up a written F93... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [F94 enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The F93... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

Textual Amendments

F93 Word in Annex 3 para. 4.5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F94 Words in Annex 3 para. 4.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(z)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the ^{F93}... declaration of conformity shall be made available to the [^{F95}enforcement authority] upon request. A copy of the ^{F93}... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

Textual Amendments

F95 Words in Annex 3 para. 4.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(z)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F88 Word in Annex 3 para. 4.5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(y)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F89 Word in Annex 3 para. 4.5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(v)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the [^{F96}enforcement authority]:

Textual Amendments

F96 Words in Annex 3 para. 4.6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the documentation referred to in point 4.3.1;
- (b) the information relating to the change referred to in point 4.3.5, as approved;
- (c) the decisions and reports of the [^{F97}approved] body referred to in points 4.3.5, 4.4.3 and 4.4.4.

Textual Amendments

F97 Word in Annex 3 para. 4.6(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

4.7. Each [^{F98}approved] body shall inform [^{F99}the Secretary of State] of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to [^{F99}the Secretary of State] the list of quality system approvals refused, suspended or otherwise restricted.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F98** Word in Annex 3 para. 4.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(w)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F99** Words in Annex 3 para. 4.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Each [^{F98}approved] body shall inform the other [^{F98}approved] bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

4.8. Authorised representative

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

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

- 5.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.5.1 and 5.6, and ensures and declares on his sole responsibility that the appliances or fittings concerned, which have been subject to point 5.3, are in conformity with the type described in the ^{F100}... type-examination certificate and satisfy the requirements of this Regulation that apply to them.

Textual Amendments

- F100** Word in Annex 3 para. 5.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances or fittings with the approved type described in the ^{F101}... type-examination certificate and with the requirements of this Regulation that apply to them.

Textual Amendments

- F101** Word in Annex 3 para. 5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.3. Verification

[^{F102}An approved] body chosen by the manufacturer shall carry out appropriate examinations and tests, or have them carried out, in order to check the conformity of the appliances or fittings with

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the approved type described in the ^{F103}... type-examination certificate and with the appropriate requirements of this Regulation.

Textual Amendments

F102 Words in Annex 3 para. 5.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(dd)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F103 Word in Annex 3 para. 5.3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant [^{F104}designated] standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the ^{F105}... type-examination certificate and with the appropriate requirements of this Regulation.

Textual Amendments

F104 Word in Annex 3 para. 5.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ee)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F105 Word in Annex 3 para. 5.4.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

In the absence of such a [^{F104}designated] standard, the [^{F106}approved] body concerned shall decide on the appropriate tests to be carried out.

Textual Amendments

F106 Word in Annex 3 para. 5.4.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.4.2. The [^{F107}approved] body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved appliance or fitting, or have it affixed under its responsibility.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F107 Word in Annex 3 para. 5.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the certificates of conformity available for inspection by the [^{F108}enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

Textual Amendments

F108 Words in Annex 3 para. 5.4.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(gg)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.5. Statistical verification of conformity

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

5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant [^{F109}designated] standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a [^{F109}designated] standard, the [^{F110}approved] body concerned shall decide on the appropriate tests to be carried out.

Textual Amendments

F109 Word in Annex 3 para. 5.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ee)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F110 Word in Annex 3 para. 5.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.5.3. The [^{F111}approved] body shall apply a sampling system with the following characteristics:

Textual Amendments

F111 Word in Annex 3 para. 5.5.3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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

The [F¹¹²approved] body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved appliance or fitting, or have it affixed under its responsibility.

Textual Amendments

F112 Word in Annex 3 para. 5.5.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the certificates of conformity at the disposal of the [F¹¹³enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

Textual Amendments

F113 Words in Annex 3 para. 5.5.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(hh)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.5.5. If a lot is rejected, the [F¹¹⁴approved] body or the [F¹¹⁵enforcement authority] shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots the [F¹¹⁴approved] body may suspend the statistical verification and take appropriate measures.

Textual Amendments

F114 Word in Annex 3 para. 5.5.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F115 Words in Annex 3 para. 5.5.5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.6. [F¹¹⁶UK] marking and F¹¹⁷... declaration of conformity
- 5.6.1. The manufacturer shall affix the [F¹¹⁸UK] marking and, under the responsibility of the [F¹¹⁹approved] body referred to in point 5.3, the latter's identification number to each individual appliance or fitting that is in conformity with the approved type described in the F¹²⁰... type-examination certificate and satisfies the applicable requirements of this Regulation.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F118** Word in Annex 3 para. 5.6.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(jj)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F119** Word in Annex 3 para. 5.6.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F120** Word in Annex 3 para. 5.6.1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

5.6.2. The manufacturer shall draw up a written ^{F121}... declaration of conformity for each appliance or fitting model and keep it at the disposal of the [^{F122}enforcement authority], for 10 years after the appliance or the fitting has been placed on the market. The ^{F121}... declaration of conformity shall identify the appliance or fitting model for which it has been drawn up.

Textual Amendments

- F121** Word in Annex 3 para. 5.6.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F122** Words in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(kk)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the ^{F121}... declaration of conformity shall be made available to the [^{F123}enforcement authority] upon request. A copy of the ^{F121}... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

Textual Amendments

- F123** Words in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(kk)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

If the [^{F124}approved] body referred to in point 5.3 agrees and under its responsibility, the manufacturer may also affix the [^{F124}approved] body's identification number to the appliance or the fitting.

Textual Amendments

- F124** Word in Annex 3 para. 5.6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F116** Word in Annex 3 para. 5.6 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(jj)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F117** Word in Annex 3 para. 5.6 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.7. If the [^{F125}approved] body agrees and under its responsibility, the manufacturer may affix the [^{F125}approved] body's identification number to the appliances or the fittings during the manufacturing process.

Textual Amendments

- F125** Word in Annex 3 para. 5.7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ff)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 5.8. Authorised representative

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

6. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

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

6.2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the [^{F126}approved] body referred to in point 6.4. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting.

Textual Amendments

- F126** Word in Annex 3 para. 6.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

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

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
- (d) a list of the [^{F127}designated] standards applied in full or in part ^{F128}..., and, where those [^{F127}designated] standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied [^{F127}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;
- (g) instructions for installation and use, for appliances;
- (h) instructions for incorporation into an appliance or for assembly, for fittings.

Textual Amendments

F127 Word in Annex 3 para. 6.2.1(d) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(mm)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F128 Words in Annex 3 para. 6.2.1(d) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(mm)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 6.2.2. Where appropriate, the manufacturer shall also submit to the [^{F129}approved] body the following documents:

Textual Amendments

F129 Word in Annex 3 para. 6.2.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- (a) the ^{F130}... type-examination certificate and the ^{F130}... declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and inspection and monitoring of the appliance or the fitting;
- (c) any other document making it possible for the [^{F131}approved] body to improve its assessment.

Textual Amendments

F130 Word in Annex 3 para. 6.2.2(a) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F131 Word in Annex 3 para. 6.2.2(c) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(II)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

The manufacturer shall keep the technical documentation at the disposal of the [^{F132}enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

Textual Amendments

F132 Words in Annex 3 para. 6.2.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(oo)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.3. Manufacturing

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

6.4. Verification

[^{F133}An approved] body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant [^{F134}designated] standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them carried out. In the absence of such a [^{F134}designated] standard [^{F135}the approved] body concerned shall decide on the appropriate tests to be carried out.

Textual Amendments

F133 Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(aa)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F134 Word in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(bb)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F135 Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(i)(cc)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

If deemed necessary by the [^{F136}approved] body, the examinations and tests may be carried out after the incorporation of the fitting, the assembly or the installation of the appliance.

Textual Amendments

F136 Word in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(II)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

The [F136 approved] body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved appliances or fittings, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the [F137 enforcement authority] for 10 years after the appliance or the fitting has been placed on the market.

Textual Amendments

F137 Words in Annex 3 para. 6.4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(pp)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.5. [F138UK] marking and F139... declaration of conformity

6.5.1. The manufacturer shall affix the [F140UK] marking and, under the responsibility of the [F141 approved] body referred to in point 6.4, the latter's identification number to each appliance or fitting that satisfies the applicable requirements of this Regulation.

Textual Amendments

F140 Word in Annex 3 para. 6.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(qq)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F141 Word in Annex 3 para. 6.5.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(ll)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.5.2. The manufacturer shall draw up a written F142... declaration of conformity and keep it at the disposal of the [F143 enforcement authority] for 10 years after the appliance or the fitting has been placed on the market. The F142... declaration of conformity shall identify the appliance or the fitting for which it has been drawn up.

Textual Amendments

F142 Word in Annex 3 para. 6.5.2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F143 Words in Annex 3 para. 6.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(rr)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

A copy of the F142... declaration of conformity shall be made available to the [F144 enforcement authority] upon request. A copy of the F142... declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F144 Words in Annex 3 para. 6.5.2 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(rr)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F138 Word in Annex 3 para. 6.5 heading substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(qq)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F139 Word in Annex 3 para. 6.5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(46)(nn)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6.6. Authorised representative

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

ANNEX IV

INSCRIPTIONS

1. In addition to the [^{F145}UK] marking referred to in Article 16, the appliance or its data plate shall bear the following information:
 - (a) the manufacturer's name, registered trade name or registered trade mark;
 - (b) the appliance type, batch or serial number of the appliance or other element allowing its identification;
 - (c) the type of electrical supply used, where applicable;
 - (d) the appliance category marking;
 - (e) the nominal supply pressure for the appliance;
 - (f) the necessary information to ensure correct and safe installation, according to the nature of the appliance.

Textual Amendments

F145 Word in Annex 4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(47)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX V

F146 ... **DECLARATION OF CONFORMITY No ...**⁽⁴⁾**Textual Amendments**

F146 Word in Annex 5 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(a)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. Appliance or fitting /appliance or fitting model (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the appliance or fitting allowing traceability; where necessary for the identification of the appliance or the fitting, an image may be included): description of the appliance or the fitting.
5. The object of the declaration described in point 4 is in conformity with the relevant [F147 statutory requirements]: ... F148

Textual Amendments

F147 Words in Annex 5 para. 5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(b)(i)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F148 Words in Annex 5 para. 5 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(b)(ii)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

6. References to the relevant [F149 designated] standards used or references to the other technical specifications in relation to which conformity is declared:

Textual Amendments

F149 Word in Annex 5 para. 6 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(c)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

7. The [F150 approved] body ... (name, address, number) ... performed ... (description of intervention) ... and issued the certificate(s): ... (details, including its date, and, where appropriate, information on the duration and conditions of its validity).

Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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Textual Amendments

F150 Word in Annex 5 para. 7 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(48)(d)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

^{F151}ANNEX VI

CORRELATION TABLE

.....

Textual Amendments

F151 Annex 6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 36 para. 2(49)** (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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Changes to legislation: Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ([OJ L 338, 13.11.2004, p. 4](#)).
- (2) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC ([OJ L 88, 4.4.2011, p. 5](#)).
- (3) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ([OJ L 330, 5.12.1998, p. 32](#)).
- (4) It is optional for the manufacturer to assign a number to the declaration of conformity.

Changes to legislation:

Regulation (EU) 2016/426 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 05 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Art. 44(4)-(6) omitted by [S.I. 2024/696 reg. 22\(3\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 2(14) words substituted by [S.I. 2019/696 Sch. 36 para. 2\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 36 para. 2(3)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(4))
- Art. 2(15) words substituted by [S.I. 2019/696 Sch. 36 para. 2\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 36 para. 2(3)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(4))
- Art. 2(16) words substituted by [S.I. 2019/696 Sch. 36 para. 2\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 36 para. 2(3)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 25(4))
- Art. 2(18) substituted by [S.I. 2019/696 Sch. 36 para. 2\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 36 para. 2(3)(b) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 2(18) words substituted in earlier amending provision S.I. 2019/696, Sch. 36 para. 2(3)(b) by [S.I. 2020/852 reg. 4\(2\) Sch. 1 para. 1\(v\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(v)(ii) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))