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ANNEX I

RISK CATEGORIES OF PPE

This Annex lays down the categories of risk against which PPE is intended to protect users.

Category I

Category I includes exclusively the following minimal risks:

- (a) superficial mechanical injury;
- (b) contact with cleaning materials of weak action or prolonged contact with water;
- (c) contact with hot surfaces not exceeding 50 °C;
- (d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- (e) atmospheric conditions that are not of an extreme nature.

Category II

Category II includes risks other than those listed in Categories I and III;

Category III

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

- (a) substances and mixtures which are hazardous to health;
- (b) atmospheres with oxygen deficiency;
- (c) harmful biological agents;
- (d) ionising radiation;
- (e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
- (f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;
- (g) falling from a height;
- (h) electric shock and live working;
- (i) drowning;
- (j) cuts by hand-held chainsaws;
- (k) high-pressure jets;
- (l) bullet wounds or knife stabs;
- (m) harmful noise.

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ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

PRELIMINARY REMARKS

1. The essential health and safety requirements laid down in this Regulation are compulsory.
2. Obligations related to essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.
3. The essential health and safety 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 health and safety protection.
4. The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment.
5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against the risks against which it is intended to protect.

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

1.1.2. Levels and classes of protection

1.1.2.1. Optimum level of protection

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

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The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness.

PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.3.4. Protective clothing containing removable protectors

Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

- (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
- (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
- (c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;

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- (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
- (f) where applicable, the type of packaging suitable for transport;
- (g) the significance of any markings (see point 2.12);
- (h) the risk against which the PPE is designed to protect;
- (i) the reference to this Regulation and, where applicable, the references to other ^{F1}relevant United Kingdom] legislation;
- (j) the name, address and identification number of the ^{F2}approved] body or bodies involved in the conformity assessment of the PPE;
- (k) references to the relevant ^{F3}designated] standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
- (l) the internet address where the ^{F4}... declaration of conformity can be accessed.

Textual Amendments

- F1** Words in Annex 2 para. 1.4(i) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(45)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Annex 2 para. 1.4(j) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(45)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Word in Annex 2 para. 1.4(k) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(45)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Annex 2 para. 1.4(l) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(45)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the ^{F5}... declaration of conformity accompanies the PPE.

Textual Amendments

- F5** Word in Annex 2 para. 1.4 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(45)(a)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

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2.2. PPE enclosing the parts of the body to be protected

PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.5. PPE which may be caught up during use

Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.7. PPE intended for rapid intervention or to be put on or removed rapidly

Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.

Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.

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2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.10. PPE for connection to complementary equipment external to the PPE

Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.

2.11. PPE incorporating a fluid circulation system

Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of ^{F6}... pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in [^{F7}English].

Textual Amendments

F6 Word in Annex 2 para. 2.12 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 35 para. 3\(45\)\(b\)\(i\)\(aa\)](#); 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in Annex 2 para. 2.12 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, [Sch. 35 para. 3\(45\)\(b\)\(i\)\(bb\)](#); 2020 c. 1, Sch. 5 para. 1(1)

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

2.13. PPE capable of signalling the user's presence visually

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PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

2.14. Multi-risk PPE

PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.

3.1.2.2. Prevention of falls from a height

PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.

Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's instructions must specify, in particular, all relevant information relating to:

- (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;
- (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.

3.1.3. Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

3.2. Protection against static compression of a part of the body

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PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.

3.3. Protection against mechanical injuries

PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.

3.4. Protection in liquids

3.4.1. Prevention of drowning

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.

Under the foreseeable conditions of use:

- (a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;
- (b) inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- (a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;
- (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- (c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.

3.4.2. Buoyancy aids

Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.

3.5. Protection against the harmful effects of noise

PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down [F8: in the Control of Noise at Work Regulations 2005 (S.I. 2005/1643) and the Control of Noise at Work Regulations (Northern Ireland) 2006 (S.R. 2006 No.1)].

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Textual Amendments

- F8** Words in Annex 2 para. 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. 35 para. 3(45)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.

3.6. Protection against heat and/or fire

PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.

3.6.1. PPE constituent materials and other components

Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.

PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

- (a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

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The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.7. Protection against cold

PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.

3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use, the following requirements apply:

- (a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.8. Protection against electric shock

3.8.1. Insulating equipment

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating,

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in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.

3.9. Radiation protection

3.9.1. Non-ionising radiation

PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.

The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.

3.9.2. Ionising radiation

3.9.2.1. Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate

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means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.

3.9.2.2. Protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.

The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).

PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

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Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

3.11. Diving equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

Where the foreseeable conditions of use so require, the diving equipment must comprise the following:

- (a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);
- (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);
- (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).

ANNEX III

TECHNICAL DOCUMENTATION FOR PPE

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

The technical documentation shall include at least the following elements:

- (a) a complete description of the PPE and of its intended use;
- (b) an assessment of the risks against which the PPE is intended to protect;
- (c) a list of the essential health and safety requirements that are applicable to the PPE;
- (d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
- (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
- (f) the references of the [F⁹designated] standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of [F⁹designated] standards, the documentation shall specify the parts which have been applied;

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- (g) where [^{F10}designated] standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
- (h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
- (i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
- (j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
- (k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
- (l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
- (m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

Textual Amendments

- F9** Word in Annex 3 point (f) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(46)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Word in Annex 3 point (g) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(46)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

ANNEX IV

INTERNAL PRODUCTION CONTROL(Module A)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable requirements of this Regulation.
2. Technical documentation

The manufacturer shall establish the technical documentation described in Annex III.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

4. ^{F11}UK] marking and ^{F12}... declaration of conformity
- 4.1. The manufacturer shall affix the ^{F13}UK] marking to each individual PPE that satisfies the applicable requirements of this Regulation.

Textual Amendments

F13 Word in Annex 4 para. 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. 35 para. 3(47)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.2. The manufacturer shall draw up a written ^{F14}... declaration of conformity for a PPE model and keep it, together with the technical documentation, at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The ^{F14}... declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the ^{F14}... declaration of conformity shall be made available to the relevant authorities upon request.

Textual Amendments

F14 Word in Annex 4 para. 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. 35 para. 3(47)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F11** Word in Annex 4 para. 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. 35 para. 3(47)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Annex 4 para. 4 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(47)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX V

^{F15}... TYPE-EXAMINATION(Module B)

1. ^{F16}... Type-examination is the part of a conformity assessment procedure in which ^{F17}an approved] body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the requirements of this Regulation that apply to it.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F16** Word in Annex 5 para. 1 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Annex 5 para. 1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2. ^{F18}... Type-examination shall be carried out by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation, plus examination of a specimen, representative of the production envisaged, of the complete PPE (production type).

Textual Amendments

- F18** Word in Annex 5 para. 2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

3. Application for ^{F19}... type-examination

The manufacturer shall lodge an application for ^{F20}... type-examination with a single [^{F21}approved] body of his choice.

Textual Amendments

- F20** Word in Annex 5 para. 3 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F21** Word in Annex 5 para. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other [^{F21}approved] body;
- (c) the technical documentation described in Annex III;
- (d) the specimen(s) of the PPE representative of the production envisaged. The [^{F21}approved] body may request further specimens if needed for carrying out the test programme. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

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

4. ^{F22}... Type-examination

The [^{F23}approved] body shall:

Textual Amendments

F23 Word in [Annex 5 para. 4](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

- (a) examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III need not be taken into account;
- (b) for PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;
- (c) for PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy;
- (d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant [^{F24}designated] standards as well as the elements which have been designed in accordance with other technical specifications;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant [^{F24}designated] standards, these have been applied correctly;
- (f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant [^{F24}designated] standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

Textual Amendments

F24 Word in [Annex 5 para. 4](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

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Textual Amendments

- F22** Word in [Annex 5 para. 4 heading](#) omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(a)** (with [Sch. 35 para. 3\(42\)](#)); 2020 c. 1, Sch. 5 para. 1(1)

5. Evaluation report

The [^{F25}approved] body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the [^{F26}Secretary of State], the [^{F25}approved] body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Textual Amendments

- F25** Word in [Annex 5 para. 5](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in [Annex 5 para. 5](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

6. ^{F27}... Type-examination certificate

6.1. Where the type meets the applicable essential health and safety requirements, the [^{F28}approved] body shall issue [^{F29}a] type-examination certificate to the manufacturer.

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

Textual Amendments

- F28** Word in [Annex 5 para. 6.1](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F29** Word in [Annex 5 para. 6.1](#) substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(48)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

6.2. The ^{F30}... type-examination certificate shall contain at least the following information:

- (a) the name and identification number of the [^{F31}approved] body;
- (b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the latter's name and address;
- (c) identification of the PPE covered by the certificate (type number);
- (d) a statement that the PPE type complies with the applicable essential health and safety requirements;
- (e) where [^{F32}designated] standards have been fully or partially applied, the references of those standards or parts thereof;

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- (f) where other technical specifications have been applied, their references;
- (g) where applicable, the performance level(s) or protection class of the PPE;
- (h) for PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model;
- (i) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;
- (j) any conditions attached to the issue of the certificate;
- (k) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19.

Textual Amendments

F31 Word in Annex 5 para. 6.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Annex 5 para. 6.2(e) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(j)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F30 Word in Annex 5 para. 6.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

- 6.3. The ^{F33}... type-examination certificate may have one or more annexes attached.

Textual Amendments

F33 Word in Annex 5 para. 6.3 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

- 6.4. Where the type does not satisfy the applicable essential health and safety requirements, the [^{F34}approved] body shall refuse to issue [^{F35}a] type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Textual Amendments

F34 Word in Annex 5 para. 6.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F35 Word in Annex 5 para. 6.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

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Textual Amendments

F27 Word in Annex 5 para. 6 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(a); 2020 c. 1, Sch. 5 para. 1(1)

7. Review of the ^{F36}... type-examination certificate
- 7.1. The [^{F37}approved] body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the [^{F37}approved] body shall inform the manufacturer accordingly.

Textual Amendments

F37 Word in Annex 5 para. 7.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(f); 2020 c. 1, Sch. 5 para. 1(1)

- 7.2. The manufacturer shall inform the [^{F38}approved] body that holds the technical documentation relating to the ^{F39}... type-examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original ^{F39}... type-examination certificate.

Textual Amendments

F38 Word in Annex 5 para. 7.2 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(e); 2020 c. 1, Sch. 5 para. 1(1)

F39 Word in Annex 5 para. 7.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(d); 2020 c. 1, Sch. 5 para. 1(1)

- 7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.
- 7.4. The manufacturer shall ask the [^{F40}approved] body to review the ^{F41}... type-examination certificate either:
- (a) in the case of a modification to the approved type referred to in point 7.2;
 - (b) in the case of a change in the state of the art referred to in point 7.3;
 - (c) at the latest, before the date of expiry of the certificate.

In order to allow the [^{F40}approved] body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the ^{F41}... type-examination certificate.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F40** Word in Annex 5 para. 7.4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F41** Word in Annex 5 para. 7.4 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

- 7.5. The [^{F42}approved] body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the [^{F42}approved] body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the ^{F43}... type-examination certificate. The [^{F42}approved] body shall ensure that the review procedure is finalised before the expiry date of the ^{F43}... type-examination certificate.

Textual Amendments

- F42** Word in Annex 5 para. 7.5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F43** Word in Annex 5 para. 7.5 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(48)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

- 7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the [^{F44}approved] body with the following:
- (a) his name and address and data identifying the ^{F45}... type-examination certificate concerned;
 - (b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant [^{F46}designated] standards or other technical specifications applied;
 - (c) confirmation that there has been no change in the state of the art as referred to in point 7.3;
 - (d) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and
 - (e) for category III products, where not already available to the [^{F44}approved] body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII, or on the results of audits of his quality system carried out in accordance with Annex VIII.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F45** Word in Annex 5 para. 7.6 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(d); 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Annex 5 para. 7.6(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(j); 2020 c. 1, Sch. 5 para. 1(1)

Where the [F44 approved] body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In such cases, the [F44 approved] body shall renew the F45 ... type-examination certificate.

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

If the [F44 approved] body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

Textual Amendments

- F44** Word in Annex 5 para. 7.6 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(f); 2020 c. 1, Sch. 5 para. 1(1)

- 7.7. If, following the review, the [F47 approved] body concludes that the F48 ... type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.

Textual Amendments

- F47** Word in Annex 5 para. 7.7 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(e); 2020 c. 1, Sch. 5 para. 1(1)
- F48** Word in Annex 5 para. 7.7 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(c); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F36** Word in Annex 5 para. 7 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(a); 2020 c. 1, Sch. 5 para. 1(1)

8. Each [F49 approved] body shall inform [F50 the Secretary of State] concerning the F51 ... type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to [F50 the Secretary

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

of State] the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Textual Amendments

- F49** Word in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(f); 2020 c. 1, Sch. 5 para. 1(1)
- F50** Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(k)(i); 2020 c. 1, Sch. 5 para. 1(1)
- F51** Word in Annex 5 para. 8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(d); 2020 c. 1, Sch. 5 para. 1(1)

Each ^{F49}approved] body shall inform the other ^{F49}approved] bodies concerning the ^{F51}... type-examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

^{F52}The Secretary of State] and the other ^{F49}approved] bodies may, on request, obtain a copy of the ^{F51}... type-examination certificates and/or additions thereto. ^{F53}The Secretary of State may on request] obtain a copy of the technical documentation and the results of the examinations carried out by the ^{F49}approved] body.

Textual Amendments

- F52** Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(k)(ii)(aa); 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in Annex 5 para. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(k)(ii)(bb); 2020 c. 1, Sch. 5 para. 1(1)

The ^{F49}approved] body shall keep a copy of the ^{F51}... type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the ^{F54}... type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the PPE has been placed on the market.

Textual Amendments

- F54** Word in Annex 5 para. 9 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 35 para. 3(48)(c); 2020 c. 1, Sch. 5 para. 1(1)

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

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX VI

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the ^{F55}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

F55 Word in Annex 6 para. 1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(49)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the ^{F56}... type-examination certificate and with the applicable requirements of this Regulation.

Textual Amendments

F56 Word in Annex 6 para. 2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(49)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

3. [^{F57}UK] marking and ^{F58}... declaration of conformity
 - 3.1. The manufacturer shall affix the [^{F59}UK] marking to each individual PPE that is in conformity with the type described in the ^{F60}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

F59 Word in Annex 6 para. 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. 35 para. 3(49)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F60 Word in Annex 6 para. 3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(49)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

- 3.2. The manufacturer shall draw up a written ^{F60}... declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The ^{F60}... declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the ^{F60}... declaration of conformity shall be made available to the relevant authorities upon request.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F57** Word in Annex 6 para. 3 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. 35 para. 3(49)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Word in Annex 6 para. 3 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(49)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX VII

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the ^{F61}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

- F61** Word in Annex 7 para. 1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the ^{F62}... type-examination certificate and with the applicable requirements of this Regulation.

Textual Amendments

- F62** Word in Annex 7 para. 2 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

3. Application for supervised product checks at random intervals

Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single [^{F63}approved] body of his choice.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F63 Word in Annex 7 para. 3 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(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;
- (b) a written declaration that the same application has not been lodged with any other [^{F63}approved] body;
- (c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the ^{F64}... type-examination, the application shall also include the following:

Textual Amendments

F64 Word in Annex 7 para. 3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

- (a) the technical documentation described in Annex III;
 - (b) a copy of the ^{F64}... type-examination certificate.
4. Product checks
- 4.1. The [^{F65}approved] body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the ^{F66}... type-examination certificate and with the applicable essential health and safety requirements.

Textual Amendments

F65 Word in Annex 7 para. 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F66 Word in Annex 7 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. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.2. The product checks shall be carried out at least once a year, at random intervals determined by the [^{F67}approved] body. The first product checks shall be carried out no more than one year after the date of issue of the ^{F68}... type-examination certificate.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F67** Word in Annex 7 para. 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F68** Word in Annex 7 para. 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. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.3. An adequate statistical sample of the manufactured PPE shall be selected by the [^{F69}approved] body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant [^{F70}designated] standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the ^{F71}... type-examination certificate and with the applicable essential health and safety requirements.

Textual Amendments

- F69** Word in Annex 7 para. 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F70** Word in Annex 7 para. 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. 35 para. 3(50)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F71** Word in Annex 7 para. 4.3 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.4. Where the [^{F72}approved] body referred to in point 3 is not the body that issued the relevant ^{F73}... type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.

Textual Amendments

- F72** Word in Annex 7 para. 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F73** Word in Annex 7 para. 4.4 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.5. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.
- 4.6. If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the ^{F74}... type-examination certificate or with the applicable essential health and safety requirements, the

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[^{F75}approved] body shall take measures appropriate to the fault(s) recorded and inform the [^{F76}Secretary of State] thereof.

Textual Amendments

- F74** Word in Annex 7 para. 4.6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F75** Word in Annex 7 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F76** Words in Annex 7 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. 35 para. 3(50)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

5. Test report

5.1. The [^{F77}approved] body shall provide the manufacturer with a test report.

Textual Amendments

- F77** Word in Annex 7 para. 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. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.

5.3. The manufacturer shall, under the responsibility of the [^{F78}approved] body, affix the [^{F78}approved] body's identification number during the manufacturing process.

Textual Amendments

- F78** Word in Annex 7 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. 35 para. 3(50)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

6. [^{F79}UK] marking and ^{F80}... declaration of conformity

6.1. The manufacturer shall affix the [^{F81}UK] marking and, under the responsibility of the [^{F82}approved] body referred to in point 3, the latter's identification number to each individual item of PPE that is in conformity with the type described in the ^{F83}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

- F81** Word in Annex 7 para. 6.1 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(50)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F82 Word in Annex 7 para. 6.1 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(50)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F83 Word in Annex 7 para. 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. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 6.2. The manufacturer shall draw up a written ^{F84}... declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The ^{F84}... declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the ^{F84}... declaration of conformity shall be made available to the relevant authorities upon request.

Textual Amendments

F84 Word in Annex 7 para. 6.2 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(50)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F79 Word in Annex 7 para. 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. 35 para. 3(50)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Word in Annex 7 para. 6 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 35 para. 3(50)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

7. 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 point 2.

ANNEX VIII

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (Module D)

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the ^{F85}... type-examination certificate and satisfies the applicable requirements of this Regulation.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F85 Word in Annex 8 para. 1 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(51)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

2. Manufacturing

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

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a single [^{F86}approved] body of his choice.

Textual Amendments

F86 Word in Annex 8 para. 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. 35 para. 3(51)(d)**; 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) the address of the manufacturer's premises where the audits can be carried out;
- (c) a written declaration that the same application has not been lodged with any other [^{F86}approved] body;
- (d) the identification of the PPE concerned;
- (e) the documentation concerning the quality system.

Where the chosen body is not the body that has carried out the ^{F87}... type-examination, the application shall also include the following:

Textual Amendments

F87 Word in Annex 8 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. 35 para. 3(51)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

- (a) the technical documentation of the PPE described in Annex III;
 - (b) a copy of the ^{F87}... type-examination certificate.
- 3.2. The quality system shall ensure that the PPE is in conformity with the type described in the ^{F88}... type-examination certificate and complies with the applicable requirements of this Regulation.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

F88 Word in Annex 8 para. 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. 35 para. 3\(51\)\(a\)](#); 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.

The quality system documentation 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 and qualification reports on the personnel concerned; and
 - (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 3.3. The [F89 approved] body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

Textual Amendments

F89 Word in Annex 8 para. 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. 35 para. 3\(51\)\(c\)](#); 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 [F90 designated] standard.

Textual Amendments

F90 Word in Annex 8 para. 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. 35 para. 3\(51\)\(e\)](#); 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 field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements.

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

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the [F⁹¹approved] body that has approved the quality system informed of any intended change to the quality system.

Textual Amendments

F91 Word in Annex 8 para. 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. 35 para. 3(51)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

The [F⁹¹approved] body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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

- 3.6. The [F⁹²approved] body shall authorise the manufacturer to affix the [F⁹²approved] body's identification number to each individual item of PPE that is in conformity with the type described in the F⁹³... type-examination certificate and satisfies the applicable requirements of this Regulation.

Textual Amendments

F92 Word in Annex 8 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. 35 para. 3(51)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F93 Word in Annex 8 para. 3.6 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(51)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

4. Surveillance under the responsibility of the [F⁹⁴approved] body
 - 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
 - 4.2. The manufacturer shall, for assessment purposes, allow the [F⁹⁵approved] body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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Textual Amendments

F95 Word in Annex 8 para. 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. 35 para. 3(51)(c)**; 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 and qualification reports on the personnel concerned.
- 4.3. The [F96 approved] body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

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Textual Amendments

F96 Word in Annex 8 para. 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. 35 para. 3(51)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.4. In addition, the [F97 approved] body may pay unexpected visits to the manufacturer. During such visits the [F97 approved] body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The [F97 approved] body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

.....

Textual Amendments

F97 Word in Annex 8 para. 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. 35 para. 3(51)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

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Textual Amendments

F94 Word in Annex 8 para. 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. 35 para. 3(51)(e)**; 2020 c. 1, **Sch. 5 para. 1(1)**

5. [F98 UK] marking and F99 ... declaration of conformity
- 5.1. The manufacturer shall affix the [F100 UK] marking and, under the responsibility of the [F101 approved] body referred to in point 3.1, the latter's identification number to each individual item of PPE that is in conformity with the type described in the F102 ... type-examination certificate and satisfies the applicable requirements of this Regulation.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Textual Amendments

- F100** Word in Annex 8 para. 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. 35 para. 3(51)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F101** Word in Annex 8 para. 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. 35 para. 3(51)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F102** Word in Annex 8 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. 35 para. 3(51)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

- 5.2. The manufacturer shall draw up a written ^{F103}... declaration of conformity for each PPE model and keep it at the disposal of the [^{F104}enforcement authority] for 10 years after the PPE has been placed on the market. The ^{F103}... declaration of conformity shall identify the PPE model for which it has been drawn up.

Textual Amendments

- F103** Word in Annex 8 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. 35 para. 3(51)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F104** Words in Annex 8 para. 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. 35 para. 3(51)(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

A copy of the ^{F103}... declaration of conformity shall be made available to the [^{F105}enforcement authority] upon request.

Textual Amendments

- F105** Words in Annex 8 para. 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. 35 para. 3(51)(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F98** Word in Annex 8 para. 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. 35 para. 3(51)(f)**; 2020 c. 1, Sch. 5 para. 1(1)
- F99** Word in Annex 8 para. 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. 35 para. 3(51)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

6. The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the [^{F106}enforcement authority]:

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Textual Amendments

F106 Words in Annex 8 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. 35 para. 3(51)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

- (a) the documentation referred to in point 3.1;
- (b) the information related to the change referred to in point 3.5, as approved;
- (c) the decisions and reports of the [^{F107}approved] body referred to in points 3.5, 4.3 and 4.4.

Textual Amendments

F107 Word in Annex 8 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. 35 para. 3(51)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

- 7. The [^{F108}approved] body shall inform [^{F109}the Secretary of State] of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to [^{F109}the Secretary of State] the list of such quality system approvals refused, suspended or otherwise restricted.

Textual Amendments

F108 Word in Annex 8 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. 35 para. 3(51)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F109 Words in Annex 8 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. 35 para. 3(51)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

The [^{F108}approved] body shall inform the other [^{F108}approved] bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.

- 8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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ANNEX IX

^{F110} ... DECLARATION OF CONFORMITY No ...⁽¹⁾**Textual Amendments**

F110 Word in Annex 9 heading omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(52)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

1. PPE (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 PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):
5. The object of the declaration described in point 4 is in conformity with the relevant [^{F111}statutory requirements]: ...

Textual Amendments

F111 Words in Annex 9 para. 5 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(52)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

6. References to the relevant [^{F112}designated] standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

Textual Amendments

F112 Word in Annex 9 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. 35 para. 3(52)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

7. Where applicable, the [^{F113}approved] body ... (name, number) ... performed the ^{F114}... type-examination (Module B) and issued the ^{F114}... type-examination certificate ... (reference to that certificate).

Textual Amendments

F113 Word in Annex 9 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. 35 para. 3(52)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

F114 Word in Annex 9 para. 7 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(52)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

8. Where applicable, the PPE is subject to the conformity assessment procedure ... (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) ... under surveillance of the [F115 approved] body ... (name, number).

Textual Amendments

F115 Word in Annex 9 para. 8 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 35 para. 3(52)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

ANNEX X

CORRELATION TABLE

Directive 89/686/EEC	This Regulation
Article 1(1)	Articles 1 and 2(1)
Article 1(2) and (3)	Article 3 point (1)
Article 1(4)	Article 2(2)
Article 2(1)	Article 4
Article 2(2)	Article 6
Article 2(3)	Article 7(2)
Article 3	Article 5
Article 4(1)	Article 7(1)
Article 4(2)	—
Article 5(1), (4), (5)	—
Article 5(2)	Article 14
Article 6	Article 44
Article 7	Articles 37-41
Article 8(1)	Article 8(2) first subparagraph

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Article 8(2)-(4)	Articles 18 and 19 and Annex I
Article 9	Articles 20, 24(1), 25, and 30(1)
Article 10	Annex V
Article 11(A)	Annex VII
Article 11(B)	Annex VIII
Article 12(1)	Article 15
Articles 12(2) and 13	Articles 16 and 17
Article 14	—
Article 15	—
Article 16(1) first subparagraph and (2)	—
Article 16(1) second subparagraph	Article 48(2)
Annex I	Article 2(2)
Annex II	Annex II
Annex III	Annex III
Annex IV	Article 16
Annex V	Article 24(2)-(11)
Annex VI	Annex IX

Changes to legislation: *There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)*

- (1) It is optional for the manufacturer to assign a number to the declaration of conformity.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) 2016/425 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Art. 24(2) substituted by [S.I. 2024/504 reg. 17\(a\)](#)
- Art. 47(4)-(6) omitted by [S.I. 2024/696 reg. 21\(5\)](#)

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

- Art. 3(2) words substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(3) words substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(a) substituted immediately before IP completion day by S.I. 2020/1460, reg. 1(4), Sch. 3 para. 24(4))
- Art. 3(5) substituted by [S.I. 2019/696 Sch. 35 para. 3\(4\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 35 para. 3(4)(b) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 3(5) words substituted in earlier amending provision S.I. 2019/696, Sch. 35 para. 3(4)(b) by [S.I. 2020/852 reg. 4\(2\) Sch. 1 para. 1\(u\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(u)(ii) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- Art. 24(2A) inserted by [S.I. 2024/504 reg. 17\(b\)](#)