REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2016

on personal protective equipment and repealing Council Directive 89/686/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,
Having regard to the opinion of the European Economic and Social Committee ([1]),
Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Council Directive 89/686/EEC ([3]) was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for personal protective equipment (PPE) in all Member States and to remove obstacles to trade in PPE between Member States.

(2) Directive 89/686/EEC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ([4]). Thus, it sets only the essential requirements applying to PPE, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([5]). Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 89/686/EEC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.

(3) Experience with the application of Directive 89/686/EEC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of that experience and to provide clarification in relation to the framework within which products covered by this Regulation may be made available on the market, certain aspects of Directive 89/686/EEC should be revised and enhanced.

(4) Since the scope, the essential health and safety requirements and conformity assessment procedures have to be identical in all the Member States there is almost no flexibility in transposing a directive based on the new approach principles into national law. Directive 89/686/EEC should therefore be replaced by a regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.

(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council [6] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(6) Decision No 768/2008/EC of the European Parliament and of the Council [7] lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with PPE presenting a risk should be adapted to that Decision.

(7) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.

(8) This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or PPE, whether new or second-hand, imported from a third country.

(9) This Regulation should apply to all forms of supply, including distance selling.

(10) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure as high a level of protection for the user of those products as for the user of PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against heat, in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal decorative products do not claim to fulfil a protective function, are by definition not personal protective equipment and are therefore not concerned by that inclusion. Clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration is not personal

protective equipment and is therefore not covered by this Regulation. As for products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, those should also fall outside of the scope of this Regulation. It is also appropriate to clarify the list of excluded PPE set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore excluded from the scope of this Regulation.

(11) Economic operators should be responsible for the compliance of PPE with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users, and to guarantee fair competition on the Union market.

(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only PPE which is in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(13) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

(15) It is necessary to ensure that PPE from third countries entering the Union market complies with the requirements of this Regulation and, in particular, that appropriate conformity assessment procedures have been carried out by manufacturers. Provision should therefore be made for importers to make sure that PPE they place on the market complies with the requirements of this Regulation and that they do not place on the market PPE which does not comply with such requirements or which present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(16) The distributor makes PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of PPE does not adversely affect the compliance of the PPE.

(17) When placing PPE on the market, every importer should indicate on the PPE his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the PPE.

(18) Efforts should be made by economic operators to ensure that all relevant documentation, such as the user's instructions, whilst ensuring precise and comprehensible information, are easily understandable, take into account technological developments and changes to end-user behaviour, and are as up to date as possible. When PPE is made available on the market in packages containing multiple units, the instructions and information should accompany each smallest commercially available unit.

(19) Any economic operator who either places PPE on the market under his own name or trademark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(20) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.

(21) Ensuring traceability of PPE throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant PPE available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with PPE or to whom they have supplied PPE.

(22) In order to simplify and adapt certain essential safety requirements of Directive 89/686/EEC to the current practice, the requirement to label PPE protecting against harmful noise with a comfort index should be removed as experience has shown that it is not possible to measure and establish such an index. As regards mechanical vibrations, it is appropriate to remove the requirement not to exceed the limit values set by Union legislation on the exposure of workers to vibrations since the use of PPE alone is not able to achieve this objective. As regards PPE protecting against radiation, it is no longer necessary to require that the instructions for use supplied by the manufacturer indicate transmission curves, since the indication of the protection factor is more useful and is sufficient for the user.

(23) It is necessary to clearly specify the relationship with, and the scope of this

Regulation as regards, the entitlement of Member States to lay down requirements for the use of PPE at the workplace, in particular pursuant to Council Directive 89/656/EEC ([8]), in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. Article 4 of that Directive obliges employers to provide PPE which complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to that Article, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation.

(24) Market surveillance authorities should have easy access to the EU declaration of conformity. In order to fulfil that requirement, manufacturers should ensure that PPE is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.

(25) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for PPE should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.

(26) In order to increase the efficiency of market surveillance, it is necessary to extend the obligation to draw up complete technical documentation to all PPE.

(27) In order to ensure that PPE is examined on the basis of the state of the art, the limit of validity of the EU type-examination certificate should be set at a maximum of five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.

(28) A simplified procedure should be applied in the case of renewal of the EU type- examination certificate where the manufacturer has not modified the approved type and the harmonised standards or other technical specifications applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art. In such cases, additional tests or examinations should not be necessary and the administrative burden and related costs should be kept to a minimum.

(29) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.

(30) In order to ensure compliance with the essential health and safety

requirements laid down in this Regulation, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three categories that are subject to different conformity assessment procedures. In order to ensure a consistently high level of safety of all PPE, the range of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.

(31) The conformity assessment procedures should be adapted to the specific conditions of the manufacture of PPE produced in series where each item is adapted to fit an individual user, and of PPE produced as a single unit to fit an individual user.

(32) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(33) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.

(34) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(35) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(36) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(37) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.

(38) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(39) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(40) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.

(41) Member States should take all appropriate measures to ensure that PPE covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons. PPE covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(42) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to PPE covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.

(43) Directive 89/686/EEC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of a

product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(44) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health or safety of persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.

(45) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(46) In order to take into account technical progress and knowledge or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the categories of risks against which the PPE is intended to protect users. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(47) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [9].

(48) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

(49) The examination procedure should be used for the adoption of implementing acts with respect to compliant PPE which presents a risk to the health or safety of persons or to other aspects of public interest protection.

(50) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.

(51) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

(52) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(53) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant PPE are justified or not.

(54) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market.

(55) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(56) Since the objective of this Regulation, namely to ensure that PPE on the market fulfils the requirements providing for a high level of protection of health and safety of users, whilst guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(57) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market,

in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union.

Article 2

Scope

1. This Regulation applies to PPE.

2. This Regulation does not apply to PPE:

(a) specifically designed for use by the armed forces or in the maintenance of law and order;

(b) designed to be used for self-defence, with the exception of PPE intended for sporting activities;

(c) designed for private use to protect against:

(i) atmospheric conditions that are not of an extreme nature,

(ii) damp and water during dishwashing;

(d) for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;

(e) for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘personal protective equipment’ (PPE) means:

(a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;

(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;

(c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use;

(2) ‘making available on the market’ means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in

return for payment or free of charge;

(3) ‘placing on the market’ means the first making available of PPE on the Union market;

(4) ‘manufacturer’ means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark;

(5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(6) ‘importer’ means any natural or legal person established within the Union who places PPE from a third country on the Union market;

(7) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;

(8) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(9) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by PPE;

(10) ‘harmonised standard’ means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(11) ‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(12) ‘national accreditation body’ means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(13) ‘conformity assessment’ means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;

(14) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(15) ‘recall’ means any measure aimed at achieving the return of PPE that has already been made available to the end-user;

(16) ‘withdrawal’ means any measure aimed at preventing PPE in the supply chain from being made available on the market;

(17) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

(18) ‘CE marking’ means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 4

Making available on the market

PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property.

Article 5

Essential health and safety requirements

PPE shall meet the essential health and safety requirements set out in Annex II which apply to it.

Article 6

Provisions concerning the use of PPE

This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE, provided that those requirements do not affect the design of PPE which is placed on the market in accordance with this Regulation.

Article 7

Free movement

1. Member States shall not impede, for the aspects covered by this Regulation, the making available on the market of PPE which complies with this Regulation.

2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the showing of PPE which does not comply with this Regulation, provided that a visible sign clearly indicates that the PPE does not comply with this Regulation and is not available on the market until it has been brought into conformity.

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

CHAPTER II
OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

6. Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

8. The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

9. Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Article 9

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the PPE has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

Article 10

Obligations of importers

1. Importers shall place only compliant PPE on the market.

2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 has been carried out by

the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not place it on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

6. When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

8. Importers shall, for 10 years after the PPE has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that

authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Article 11

Obligations of distributors

1. When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

4. Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where the PPE presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set

out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with this Regulation may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with PPE;

(b) any economic operator to whom they have supplied PPE.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the PPE and for 10 years after they have supplied the PPE.

CHAPTER III
CONFORMITY OF THE PPE

Article 14

Presumption of conformity of PPE

PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.

Article 15

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IX, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is placed or made available on the market.

3. Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the PPE with the requirements laid down in this Regulation.

Article 16

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 17

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.

2. The CE marking shall be affixed before the PPE is placed on the market.

3. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER IV
CONFORMITY ASSESSMENT

Article 18

Risk categories of PPE

The PPE shall be classified according to the risk categories set out in Annex I.

Article 19

Conformity assessment procedures

The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:

(a) Category I: internal production control (module A) set out in Annex IV;

(b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI;

(c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:

(i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII;

(ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in point (b) may be followed.

CHAPTER V
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 21

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 23

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 24

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the

designer, manufacturer, supplier, purchaser, owner, user or maintainer of the PPE which they assess, nor the representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment

activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes V, VII and VIII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes V, VII and VIII.

Article 27

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 29

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 30

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take

appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 32

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the requirements of this Regulation.

3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

4. Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, a notified body finds that a PPE no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

Article 33

Appeal against decisions of notified bodies

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Article 34

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 36

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

CHAPTER VI
UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 37

Union market surveillance and control of PPE entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2(1) of this Regulation.

Article 38

Procedure at national level for dealing with PPE presenting a risk

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the PPE to meet requirements relating to the health or safety of persons; or

(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay.

Article 39

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 40

Compliant PPE which presents a risk

1. Where, having carried out an evaluation under Article 38(1), a Member State finds that although PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 41

Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;

(d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;

(e) the technical documentation is either not available or not complete;

(f) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;

(g) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VII
DELEGATED AND IMPLEMENTING ACTS

Article 42

Delegated power

1. In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Commission shall be empowered to adopt delegated acts in accordance with Article 43 in order to amend Annex I by reclassifying the risk from one category to another.

2. A Member State which has concerns about the classification of a risk into a specific risk category referred to in Annex I shall immediately inform the Commission of its concerns and provide reasons in support.

3. Prior to adopting a delegated act, the Commission shall carry out a thorough assessment of the risks that require reclassification and the impact of such reclassification.

Article 43

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for a period of five years from 21 April 2018. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The delegation of powers referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 44

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

CHAPTER VIII
TRANSITIONAL AND FINAL PROVISIONS

Article 45

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them.

2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.

Article 46

Repeal

Directive 89/686/EEC is repealed with effect from 21 April 2018.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex X.

Article 47

Transitional provisions

1. Without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in

conformity with that Directive and which were placed on the market before 21 April 2019.

2. EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date.

Article 48

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. This Regulation shall apply from 21 April 2018, with the exception of:

(a) Articles 20 to 36 and Article 44, which shall apply from 21 October 2016;

(b) Article 45(1), which shall apply from 21 March 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 March 2016.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
J.A. HENNIS-PLASSCHAERT

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(1) OJ C 451, 16.12.2014, p. 76.

(2) Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

(3) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

(4) OJ C 136, 4.6.1985, p. 1.

(5) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

(6) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(7) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(8) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

(9) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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.

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

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;

(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 Union harmonisation legislation;

(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;

(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;

(l) the internet address where the EU declaration of conformity can be accessed.

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

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.

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.

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 harmonised 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 a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

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

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

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 by Directive 2003/10/EC of the European Parliament and of the Council [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.

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, 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 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.

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).

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(1) Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 42, 15.2.2003, p. 38).

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 harmonised 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 harmonised standards, the documentation shall specify the parts which have been applied;

(g) where harmonised 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.

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.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written EU 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 EU declaration of conformity shall identify the PPE for which it has been drawn up.

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

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

EU TYPE-EXAMINATION

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified 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.

2. EU 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).

3. Application for EU type-examination

The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.

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 notified body;

(c) the technical documentation described in Annex III;

(d) the specimen(s) of the PPE representative of the production envisaged. The notified 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.

4. EU type-examination

The notified body shall:

(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 harmonised 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 harmonised 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 harmonised 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.

5. Evaluation report

The notified 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 notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. EU type-examination certificate

6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU 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.

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

(a) the name and identification number of the notified 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 harmonised standards have been fully or partially applied, the references of those standards or parts thereof;

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

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

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

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

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

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

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

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

7. Review of the EU type-examination certificate

7.1. The notified 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 notified body shall inform the manufacturer accordingly.

7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU 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 EU type-examination certificate.

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 notified body to review the EU 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 notified 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 EU type-examination certificate.

7.5. The notified 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 notified body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.

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 notified body with the following:

(a) his name and address and data identifying the EU 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 harmonised 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 notified 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.

Where the notified 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 notified body shall renew the EU type-examination certificate.

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

If the notified 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.

7.7. If, following the review, the notified body concludes that the EU 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.

8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On a reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU 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 EU 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.

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.

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 EU type-examination certificate and satisfies the applicable requirements of this Regulation.

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 EU type-examination certificate and with the applicable requirements of this Regulation.

3. CE marking and EU declaration of conformity

3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

3.2. The manufacturer shall draw up a written EU 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 EU declaration of conformity shall identify the PPE for which it has been drawn up.

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

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 EU type-examination certificate and satisfies the applicable requirements of this Regulation.

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 EU type-examination certificate and with the applicable requirements of this Regulation.

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 notified body of his choice.

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 notified body;

(c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

(a) the technical documentation described in Annex III;

(b) a copy of the EU type-examination certificate.

4. Product checks

4.1. The notified 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 EU type-examination certificate and with the applicable essential health and safety requirements.

4.2. The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type-examination certificate.

4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified 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 harmonised 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 EU type-examination certificate and with the applicable essential health and safety requirements.

4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.

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 EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take

measures appropriate to the fault(s) recorded and inform the notifying authority thereof.

5. Test report

5.1. The notified body shall provide the manufacturer with a test report.

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 notified body, affix the notified body's identification number during the manufacturing process.

6. CE marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified 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 EU type-examination certificate and satisfies the applicable requirements of this Regulation.

6.2. The manufacturer shall draw up a written EU 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 EU declaration of conformity shall identify the PPE model for which it has been drawn up.

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

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 EU type-examination certificate and satisfies the applicable requirements of this Regulation.

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 notified body of his choice.

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 notified 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 EU type-examination, the application shall also include the following:

(a) the technical documentation of the PPE described in Annex III;

(b) a copy of the EU type-examination certificate.

3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate and complies with the applicable requirements of this Regulation.

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 notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

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 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 notified body that has approved the quality system informed of any intended change to the quality system.

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

4. Surveillance under the responsibility of the notified 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 notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.

4.3. The notified 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.

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

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified 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 EU type-examination certificate and satisfies the applicable requirements of this Regulation.

5.2. The manufacturer shall draw up a written EU 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 EU declaration of conformity shall identify the PPE model for which it has been drawn up.

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

6. The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information related to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. The notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted.

The notified body shall inform the other notified 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.

ANNEX IX

EU DECLARATION OF CONFORMITY No 1

1. PPE (product, type, batch or serial number): Cocoon 5

2. Name and address of the manufacturer and, where applicable, his authorised representative: ART GmbH, Pilotenstraße 2, 49419 Wagenfeld, Germany

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: ART GmbH, Pilotenstraße 2, 49419 Wagenfeld, Germany

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 Union harmonisation legislation:

   product norm and ppe regulations

6. References to the relevant harmonised 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:

DIN EN 12278: 08-2007

7. The notified body TÜV SÜD Product Service GmbH, CE0123 performed the EU type-examination (Module B) and issued the EU type-examination certificate P5A 001321 0010 Rev. 00.

8. The PPE is subject to the conformity assessment procedure :

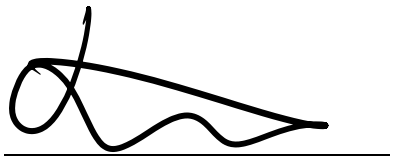
   conformity to type based on internal production control plus supervised product checks at random intervals (Module D) under surveillance of the notified body TÜV SÜD Product Service GmbH, CE0123.

9. Additional information:

Signed for and on behalf of: ART GmbH, Lea Windten

(place and date of issue): Wagenfeld, 30.09.2020

(name, function) (signature): Lea Windten, CEO



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

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
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