Conformity assessment procedures for the Personal Protective Equipment Scheme

RD_111, Issue 05

This scheme document describes the conformity assessment procedures and requirements for Personal Protective Equipment for placing them on the European market

Revision record sheet

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet

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01	-	-		Complete overhaul of previous RD_110 to accommodate the change from PPE directive into the PPE regulation	GG / WJJ
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1 Introduction

1.1 About Kiwa Certification

Kiwa Certification is a third party test laboratory and a third party certification and inspection body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited Kiwa Certification to ISO/IEC 17025 (laboratory) and EN 17065 (product certification). This procedure is under the scope of these accreditations.

Specialising in the area of complex electronic equipment the activities of the Certification department cover product and quality system certification as well as product inspection.

Furthermore, Kiwa offers services for obtaining national approvals in various countries and a package of test services. More information about Kiwa is available in *RD_560, About Kiwa.*

1.2 About this document

This document lays down the procedures for manufacturers and importers who want to place Personal Protective Equipment (PPE) products under the scope of the Personal Protective Equipment Regulation on the market of the European Union plus Iceland and Norway.

Described are the conformity assessment procedures that have to be followed before these products may be placed on the market and how to act when modifications to such products are made. It also describes specific conditions, such as CE markings, Declarations of Conformity, which manufacturers and importers will have to deal with.

These conformity assessment procedures are derived from the European Personal Protective Equipment Regulation (EU) 2016/425 (PPE Regulation). The PPE Regulation was published 9 March 2016 and came into force on 21 April 2016. This PPE Regulation repeals the former Personal Protective Equipment Directive 89/686/EEC per 21 April 2016.

1.3 Transition from Directive into Regulation.

The PPE Regulation has been published in the Official Journal of the European Commission on 31 March 2016. The PPE Directive 89/686/EEC has been repealed on 21 April 2016, and the new PPE Regulation (EU) 2016/425 is active as of that date.
The Regulation has entered into force on 21 April 2016 and all member states must apply the new Regulation as of that date. The transition period in which either the directive 89/686/EEC or the regulation (EU) 2016/425 can be applied, will expire on 21 April 2019.

The following transition provisions apply:

1. 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.

Take note that according to NLF, the concept of placing on the market, holds for every individual product. Hence, all individual pieces of equipment placed on the market as per 21 April 2019, must meet the requirements of the PPE Regulation. That also concerns placement of pieces of equipment equal to pieces which were already placed on the market before 21 April 2019 under the PPE Directive.
Under the new Regulation, Notified Bodies (NBs) will issue an EU-type examination Certificate.

Timeline (Directive into Regulation):

Publication Regulation	Regulation into force (Either Regulation or Directive can be applied)	End transition period (Only Regulation may be applied as of this date)	All certificates issued under the Directive will expire (if not expired already)
31-03-2016	21-04-2018	21-04-2019	21-04-2023

2 European regulations

2.1 Introduction

The policy objectives of the first harmonization of EU Regulations and directives, concentrating on the elimination of trade barriers and on the free movement of goods for the development of a single market, are now being balanced out by a comprehensive policy geared to ensuring that only safe and compliant products find their way to the market, in such a manner that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of the EU consumer and a competitive single EU market.

Policy orientations and legislative techniques alike have profoundly changed in the last 35 years of European integration, especially in the area of the free movement of goods, contributing to make this area of activity a symbol of the success of the Single Market today.

Historically, EU legislation for goods has progressed through four main phases:

- the traditional approach or 'Old Approach' with detailed texts containing all the necessary technical and administrative requirements;
- the development of the 'New Approach' in 1985, which restricted the contents of legislation to the "essential requirements" leaving the technical details to European harmonised standards. This in turn led to the development of the European standardisation policy in support of this legislation;
- the development of the conformity assessment instruments made necessary by the implementation of the various Union harmonisation texts, both 'new approach' and 'old approach', leading to the ‘Global approach” as described in Council Decision 93/465/EEC of 22 July 1993;
- the 'New Legislative Framework'[1] adopted in July 2008, which builds on the 'New Approach' and completes the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from third countries.

2.2 The New Legislative Framework (NLF)

This is a general framework of a horizontal nature for future legislation harmonizing the conditions for the marketing of products and a reference text for existing legislation.

In the 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[2], and repealing Council Decision 93/465/EEC provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. The Annex I of this document shows the different responsibilities of manufactures (Article R1), authorized representatives (Article R2), Importers (Article R4) and distributors (Article R5).

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[3] and repealing Regulation (EEC) No 339/93. This regulation lays down rules on the organization and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It also provides a framework for the market surveillance of products to ensure that those products fulfill requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security and provides a framework for controls on products from third countries. This Regulation lays down the general principles of the CE marking.

[1] Regulation 765/2008 and Decision 768/2008/EC
[2] OJ L 218, 13.8.2008, p. 82
[3] OJ L 218, 13.8.2008, p. 30

Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. The aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of goods. This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or intending to take a decision, which would hinder the free movement of a product lawfully marketed in another Member State. It also provides for the establishment of Product Contact Points in the Member States to contribute to the achievement of the aim of this Regulation.

2.3 The NLF and PPE Regulation

The PPE Regulation should take into account of the horizontal legal framework for the marketing of products in the internal market, established by 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 as well as by 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.

2.3.1 Economic operators

Four economic operators are defined: Manufactures, Authorized representatives, Importers and Distributors. The economic operators have different obligations (a summary is given in table1), which are in line with the NLF (Decision No 768/2008/EC). Articles 8 – 13 of the PPE Regulation mention the obligations of the economic operators.

A new requirement of the PPE Regulation is the mandate to provide more contact information for the economic operators. EU Member States will require the economic operators to include both website addresses and physical location postal addresses, in order to facilitate better communications between the member states, market surveillance authorities, economic operators, and consumers. The equipment must show the product identification numbers and contact information for the responsible parties. A contact name and details must be supplied with each device, and also placed on the device or in documentation if it is a small device. Importers must show similar information on the equipment or on the packaging; the supply chain must accept the legal responsibility for providing valid contact information.
Importers will be seen as manufacturers when placing products under their own name, brand name or changing the equipment.

Economic operators shall, on request, identify the following to the market surveillance authorities:
- Any economic operator who has supplied them with the PPE.
- Any economic operator to whom they supplied PPE.

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

More summarizing information about the obligations of Economic Operators can be found in table 1.

	Manufacturer	Authorised representative	Importer	Distributor
Design and manufactured conform essential requirements	YES			
Placing on the market only when comply to essential requirements	YES		YES	YES
Carry out the relevant conformity assessment procedure	YES, or have it carried out		Ensure it is carried out	
Technical Documentation	Issue and 10 years filling and providing	Yes 10 years filling and providing	Ensure it is drawn up and 10 years filling and providing	Verify
DOC	Issue and 10 years filing	10 years filling and providing	10 years filling and providing	Verify
CE mark	Affix		Ensure	Verify
Type, serial number, id	On equipment (or package or documentation for very small equipment)		Ensure	Verify
Name,tradename or registered trade mark postal address	On equipment (or package or documentation for very small equipment)		Check details + add postal importer.	Verify details manuf. + importer
Manual and user restrictions.	Issue + add to equipment.		Ensure	Verify
Continuous compliance of series production	Have a procedure to ensure series production in compliance			
Corrective actions on Non-compliances	Corrective measures	Corrective measures	Corrective measures	Corrective measures
Inform National authorities when risk.	YES		Yes+ manufactur er	Yes+ manufactur er
Cooperation National authorities	YES	YES	YES	YES
Cooperation National Authorities for market surveillance	YES + 10year	YES + 10year	YES + 10year	YES + 10year

Table 1: Economic operators and different aspects of the certification process

2.4 The scope of the PPE Regulation

The PPE Regulation (EU) 2016/425 applies to personal protective equipment, hereinafter referred to as 'PPE'.
It lays down the conditions governing its placing on the market and free movement within the Community and the basic safety requirements which PPE must satisfy in order to ensure the health protection and safety of users.

For the purposes of the PPE Regulation, PPE shall mean:

(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;

The PPE 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-defense, 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.

The scope of Kiwa regarding the PPE is limited to harmonised standards, as listed in the Official Journal of the European Communities, for head protection.

This scope is defined on the NANDO website at this address:
http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=6

2.5 Essential requirements

Equipment within the scope of the PPE Regulation must meet the essential health and safety requirements.
In Annex II of the PPE Regulation the essential requirements for Personal Protective Equipment are stated.
PPE that does meet the essential requirement will be given a declared complaint. Compliance is a result from a conformity assessment procedure.

2.6 Conformity assessment

All items of equipment within the PPE scope, placed on the European market for the first time must follow one of the conformity assessment procedures.

Conformity assessment means the process demonstrating whether the essential requirements (as mentioned in Article 5 of the Regulation) relating to PPE have been fulfilled.
So compliance is against Essential requirements, not standards. However PPE which is in conformity with harmonised standards shall be presumed to be in conformity with the essential requirements. There does not need to be a harmonised standard to apply one of the Conformity Assessment Procedures. The Essential Requirements apply even in the absence of harmonised standards.
The manufacturer shall perform a conformity assessment of the PPE before putting his equipment on the European market. In order to be legally used in the European market, equipment must comply with the requirements of the Regulation.

In Article 19 of the PPE Regulation the conformity assessment procedures are explained. The manufacturer can use either Module A, Module B+C, Module B+C2 or Module B+D.

The conformity assessment shall take into account for all intended operating conditions the essential requirements (Health & safety).The assessment shall also take into account the reasonably foreseeable conditions. Where the PPE is capable of taking different configurations, the conformity assessment shall confirm whether the PPE meets the essential requirement in all possible configurations.

2.7 Bodies involved in the conformity assessment

Although responsibility for conformity assessment lies entirely with the manufacturer, the PPE makes it obligatory to enlist the services of a third party. The various parties involved in the field of testing and certification all have their own tasks and responsibilities.

2.7.1 The Test Laboratory

Products falling under the scope of the PPE have to be tested by a laboratory designated by one of the Member States in the European Union. A list of Test Laboratories notified under the PPE by the Member States to the European Commission can be found on Nando. Enter in the last field (named: Keyword on Legislation) of the link: http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=search.main "2016/425" and push the Search button. A list of all Notified Test Laboratories will be listed.

For test laboratory results to be accepted by Kiwa it is necessary that the test laboratory is accredited. For non accredited laboratories, audits on site have to be performed by Kiwa, to ensure the testing is compliant with ISO/IEC 17025 and applicable standards. In case of selecting accredited test laboratory, the scope of accreditation will be reviewed to ensure that related tests are covered by the scope of accreditation. New test lab partners must be announced to the ministry of SZW and or VWS for their approval.

2.7.2 The Notified Body

A Notified Body is a third party who is authorised to implement the tasks relating to certification as specified in a European Directive. A Notified Body can be regarded as a competent certification body in a field where certification of a product is legally compulsory. A Notified Body is designated by a Member State. A Member State of the EEA (European Economic Area) can only designate bodies that fall within its sphere of competence.

The bodies designated by Member States should satisfy certain criteria regarding proficiency, independence, impartiality, etc. In this respect, standards like ISO/IEC 17020, ISO/IEC 17025, ISO/IEC 17065 are particularly important. The body is then notified to the European Commission and the other Member States of the EEA and thereby acquires the status of 'Notified Body'.

2.8 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.

2.9 The 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.

2.10 Coordination of notified bodies

According article 36 of the PPE Regulation notified bodies are obliged to take part in sectoral notified body group. In the sector PPE the applicable notified body group is:

- European Coordination of Notified Bodies for Personal Protective Equipment.

Kiwa has joined this group and will actively contribute. Kiwa will continue contribution in this groups in future. Kiwa follows the Recommendations for Use (RfU) as published by the horizontal committee and the applicable vertical groups (VG's).

3 Conformity assessment procedures of the PPE Regulation

3.1 Overview

To prove products comply with the essential requirements of the PPE Regulation, the PPE at hand must be classified. The categories are based on the risk against which PPE is intended to protect users. There are three distinct risk categories and their relevant conformity assessment procedures.

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.

For each category the applicable conformity assessment procedure is show a flow diagram in the next figure:

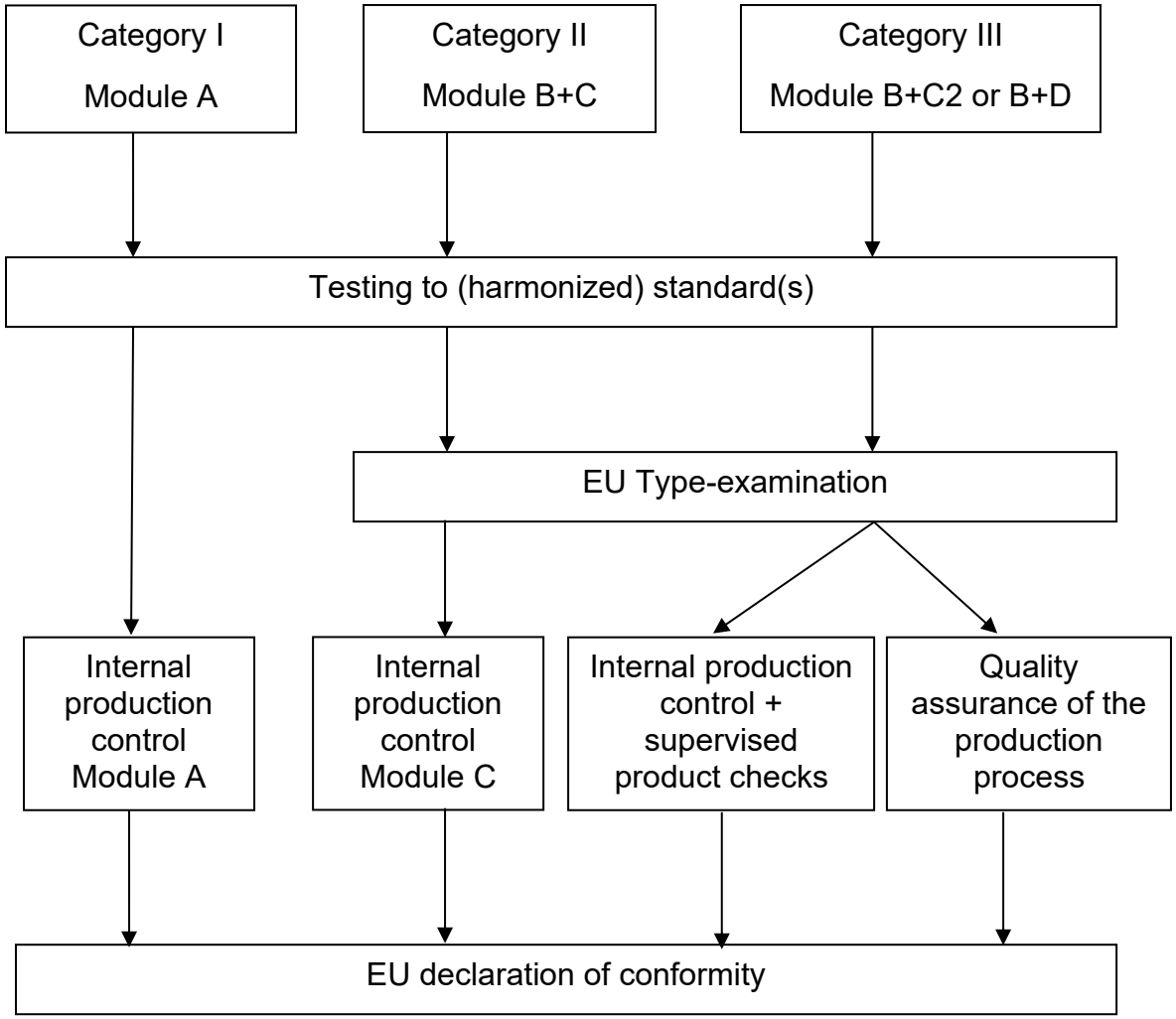

Figure 1: Flow diagram conformity assessment procedure of PPE

3.2 The various conformity assessment procedures

Three conformity assessment procedures are given in the PPE Regulation. These procedures are based on different Categories:

- Category I: internal production control (module A) set out in Annex IV of the PPE Regulation;
- 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;
- 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 as for Category II may be followed.

For PPE certification by Kiwa of helmets the conformity assessment procedure of Category II products is applicable. This conformity procedure is further described in section 3.4.

3.3 Category I products: Module A

The procedure of Internal production control (Module A) must be used for products as defined in Annex IV of the regulation and can be done by the manufacturer himself.

3.4 Category II products: Module B+C

This procedure must be used for products neither category I or III. A notified body performs the module B and Module C must be performed by the manufacturer.

3.4.1 Module B: EU Type-examination

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 harmonized 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
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.

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.
More details are given in section 4.4.

7. Review of the EU type-examination certificate

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. 31.3.2016 L 81/89 Official Journal of the European Union EN 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 documentation 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.

3.4.2 Module C: Conformity to type based on internal production control

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 below, 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 the PPE 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 the PPE 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 the PPE 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.

3.5 Category III products: Module B+C2 or B+D

This procedure must be used for products as defined in Annex VII (Module B+C2) or Annex VIII (B+D) and must be performed in cooperation of manufacturer and notified body.

3.5.1 Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals

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.

3.5.2 Module D: Conformity to type based on quality assurance of the production process

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.

3.6 Compliant with regulation 2016/425/EU

The laboratory in charge to submit the test results to Kiwa of PPE products will be reviewed initially in accordance article 26 and article 24 of regulation 2016/425/EU. In case enough evidence is available that the laboratory complies with the related articles, the laboratory will be listed in an overview (approved customer laboratories). In case article 24 of regulation 2016/425/EU cannot be met Kiwa must be informed immediately.
Review will be conducted by Kiwa once in the 5 years.

4 The application

4.1 Required documentation

The (technical) documentation to be submitted with the application must contain the information necessary to assess the product, such as:

- ❖ General information according the PPE Regulation:

  - the name and address of the manufacturer or his authorized representative
  - the PPE production plant in question
  - identification of the product (type, batch or serial number or other element allowing identification)
  - a description of the product
  - Declaration of Conformity

- ❖ The manufacturer's technical documentation according annex III of the PPED

- ❖ Appropriate number of specimens of the model to be approved

If the applied product is a Category III product, the technical documentation, should additionally contain:

- all test reports
- information concerning the quality manual
- plans
- description of the products and the manufacturing process
- the quality management system standards applied etc.

→ To start an application and to be able to accept the application a set of documents need to be provide to Kiwa, preferably in a digital format like PDF or MS Word. The required documentation exhibits are indicated in document *RX_110 Quick reference guide PPE*.

Kiwa will use the documentation and test results to ascertain whether the equipment satisfies all the (essential) requirements.

4.2 Terms for application acceptation or rejection and decision deadline

For this PPE scheme rules for terms regarding application acceptation or rejection and decision deadlines are according chapter 4 of the Algemene wet bestuursrecht[4].

4.3 Product variants

A product may be marketed in different variations, however all of these variations need to be assessed by Kiwa. OEM products and product variants can be added to a Certificate of Conformity if they comply with the following conditions.

Product
A product is equipment that is unique in its construction.
OEM product
One may market the same product under different type designations and/or trademarks. The products are 100% identical, in construction, hardware, software and physical outlining (OEM = Original Equipment Manufacturer).

Product variants

- These products only differ on points that have no noticeable influence on the expected protective performances.

[4] http://wetten.overheid.nl/BWBR0005537/2017-09-01

- For each of the variants identified, the manufacturer must provide a detailed description indicating the differences in comparison with the reference model and the number of samples of the variants required to complementary checks and tests.

The variant can be extended to the existing EU type-examination certificate or for the variant a new EU type-examination certificate can be issued.

4.4 The EU Type-Examination Certificate

If the conformity assessment procedure has been completed successfully, and the product meets the applicable essential health and safety requirements an EU type-examination certificate will be issued. Next to the name and address of the manufacturer and certificate holder and data to identify the equipment, the EU type-examination certificate will contain the elements a defined in annex V of the PPE Regulation.
The annexes accompanying the certificate contain information on the technical specifications on the basis of which the EU type-Examination Certificate was issued and any conditions for its validity.

The standard validity period of the certificate is 5 years, but can be chosen to be smaller where applicable.

A model of the EU type-Examination Certificate can be found in annex B. This certificate is not transferable without the intervention of Kiwa. See also *'Modifications following certification'.*

The manufacturer and where applicable the certificate holder are obliged to keep the technical documentation and the EU type-Examination Certificate and any addition(s) for at least ten years after the last product has been manufactured. See also *'The technical documentation'.*

4.5 General requirements

This section describes 'The declaration of conformity', 'The technical documentation' and 'The affixing of marking' requirements that do apply to all aforementioned procedures.

4.5.1 The EU Declaration of Conformity

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

The EU declaration of conformity shall have the model structure set out in Annex IX of the PPE Regulation, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII of the PPE Regulation 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.

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.

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 the PPE Regulation.

A model of the Declaration of Conformity is given in annex IX of the Regulation. A copy of the model can also be found in annex C of this scheme.

4.5.2 The technical documentation

The manufacturer must compile a technical documentation. The manufacturer or his authorised representative in the EEA should keep this file for at least 10 years after the last product has been manufactured. If the manufacturer is not established in the EEA and has not appointed a representative, the file must be kept by the person who has placed the product on the market. The file is primarily intended for inspections carried out by competent national government authorities. See also chapter *The Technical documentation*.

4.5.3 The affixing of markings

The PPE Regulation states that a CE marking consisting of the initials CE must be affixed to every product placed on the market of the EEA in accordance with all the provisions of the NLF (Article 30 of Regulation (EC) No 765/2008). (see also the section *'Markings'*). The initials CE only need to be affixed once, even if several Directives or Regulations apply.

4.6 Expiration, suspension and withdrawal of certificates

Any certificate issued by Kiwa may immediately be suspended or withdrawn by Kiwa when:

- CE markings are abused by the certificate holder, or;
- non-conformities due to an error during the EU type-examination procedure or;
- non-conformities in the application of the Regulation or;
- complaints are received from e.g. the purchasers, regarding marketed products and these complaints are substantiated by supplementary examinations that reveal non-compliances or;
- a presumption arises that the marketed products oppose an immediate direct danger to users;
- withdrawal is requested by the national authorities who have the power to supervise and enforce the Law or;
- withdrawal is requested by the certificate holder.

Any certificate expires when:

- the certificate is replaced by another certificate, or;
- the certificate is withdrawn by Kiwa.
- The certificate reaches expiry date.

The certificate holder is informed of intended as well as actual suspension and withdrawal in writing. In such cases the manufacturer may no longer apply CE markings to *any* product involved. Withdrawal may result in the manufacturer being obliged to recall all associated products from the market. In case of suspension the conditions for resume are included.

In RQ_160 is defined for the related possibilities e.g. termination, suspension and reduction which action must be taken and how these actions have to be performed.

4.6.1 Informing the applicable ministry

When a presumption arises that the marketed products oppose an immediate direct danger to the safety of users, Kiwa will directly inform the applicable ministry SZW or VWS (via NVWA). Also other possible stakeholders may be informed and in particular a stakeholder that can resolve the presumed danger.

In case of any suspension or withdrawal of certificates, Kiwa will inform directly the applicable ministry. SZW will be contacted directly. VWS will be contacted via the NVWA.

4.7 Point of view, appeal and complaint procedures

For this PPE scheme the following procedures are applicable:

- Point of view procedure (“zienswijze procedure”) according 4.1.2 of Algemene wet bestuursrecht[5]
- Appeal procedure according chapter 6 and 7 of Algemene wet bestuursrecht
- Complaint procedure according chapter 9 of Algemene wet bestuursrecht

Applicants will be informed of their right for appeal and complaint together with each issued decision.

[5] http://wetten.overheid.nl/BWBR0005537/2017-09-01

4.8 Maintenance of certificates

The issued EU type-examinations will be kept permanently in archived digital records. Along with the certificate all used technical documentation, declarations and reports will be stored permanently.

All issued EU type-examinations will be added to the publication list on the Kiwa website:
Search radio, wireless and electrical equipment certificates (kiwa.com)

4.9 Termination of activities under the PPE scheme

In case Kiwa will decide to terminate the activities under this PPE scheme, according the WDA&T, the minister of Sociale Zaken en Werkgelegenheid (SZW) will be directly informed. The minister has to decide what has to be done with all the records.

For archived records falling under the responsibility of the minister of Volksgezondheid, Welzijn en Sport (VWS), Kiwa will inform VWS via the Nederlandse Voedsel- en Warenauthoriteit.

5 Modifications following certification

5.1 Types of modifications

One or more of the following types of modifications may be involved.

Modifications of an administrative nature:
- changes to the details of the certificate holder;
- change of certificate holder;
- alteration/addition of a type designation and/or trademark.

Modifications of a technical nature:
- addition of new product variants;
- modifications related to a product where the products is modified in a way that affects, or may affect, conformity with the essential requirements;
- modifications not affecting the essential requirements.

5.2 Changes to the details of the certificate holder

In this case, the certificate holder remains the same, but there are changes, for example, to his address, website or telephone number. The certificate holder should inform Kiwa of the changes as quickly as possible.

Comments
Modification does not affect the conformity. Kiwa will record the new details and send the applicant a confirmation. Certificates already issued remain unchanged.

5.3 Change of certificate holder

The EU type-examination Certificate is drawn up in the name of the certificate holder and is not transferable without the intervention of Kiwa. The name of the certificate holder can, however, be changed, in which case the new certificate holder automatically assumes all the responsibilities and obligations applicable under the issued EU type-examination certificate in question.

Comments
The original holder of the certificate(s) must notify Kiwa in writing that the product should be transferred to the name of the new certificate holder.[6] All the type designations and certificate numbers to which the transfer applies should be listed.

The new holder of the certificate(s) should inform Kiwa in writing that he is taking over the EU type-examination certificate in question, and should list all the types and certificate numbers. He should also declare, and if necessary demonstrate, that he will fulfil all the responsibilities and obligations applicable under the original type-examination. The new certificate holder draws up a Declaration of conformity for each type and sends a copy to Kiwa.

Kiwa will issue a follow-up *to the EU type-examination certificate*, in which the details of the new certificate holder are stated.

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6 If the holder has been declared bankrupt, the receiver is the approval-holder.

5.4 Alteration/addition of a type designation and/or trademark

Alteration/addition of a type designation and/or trademark means that the hardware or software remains unchanged but the type designation and/or trademark under which the product is marketed is replaced by, or extended with, a new type designation.

Comments
In this case, the old type designation and/or trademark is replaced by a new one. It is also possible to market a product under both the old and new type designation and/or trademark. This applies to OEM products.

The approval holder should notify Kiwa in writing of the alteration or addition of the type designation and/or trademark and declare that the new type(s) are identical to the already approved type. He should also indicate the old type designation and/or trademark and the approval/registration number and new type designation and/or trademark.

A follow-up to the EU type-examination certificate will be issued to the certificate holder. All the relevant type designations and/or trademarks are listed in an annex.

5.5 Addition of new product variants

Addition of new product variants means that a new product variant is added to a type. The variants must all be based on the same design and may differ only in options, version, etc.

Comments
It is possible to place several product variants under one EU type-examination certificate, each having its own type designation and/or trademark. However, the variants must form a product family, i.e. the variations in the products must be based on the same design. It must be possible to demonstrate that the variants belong to the same type, e.g. by means of a technical examination by a designated laboratory.

The manufacturer or importer draws up a new *Declaration of conformity* and sends a copy to Kiwa. Kiwa issues a follow-up to the EU type-examination certificate, in which the relevant type designations and/or trademarks are listed.

5.6 Modifications not affecting the essential requirements

Technical, editorial and cosmetic modifications made to products already certified that will not affect conformity with the essential requirements AND if address details of the manufacturer and applicant remain unchanged AND if the product description, type designation, hardware/firmware/software versions remain unchanged, THEN it is not needed to notify (inform) Kiwa. However, if any modification does affect one or more of the items mentioned, adequate information about the change(s) need to be provided to Kiwa.
Kiwa shall be informed in case there is any doubt about this.

6 The technical documentation

6.1 Introduction

The PPE Regulation (and other EU Directives or Regulations) requires the manufacturer to compile a file with the Technical documentation. This file should contain all the data that can be used to show that the product conforms to the requirements of these Directives or Regulations.

This section provides further information on the scope, content and form of the technical documentation.

6.2 Purpose of the technical documentation

The technical documentation plays a key role in the conformity assessment of a product. The manufacturer in co-operation with the approved bodies assesses the product and keeps the (test) data in a file with all the technical documentation.

The file compiled by the manufacturer is primarily intended for the national authorities responsible for inspections. The national authorities have the right to require the manufacturer or importer to provide data showing that a product satisfies the requirements of a Directive. If the manufacturer or importer is unable or unwilling to supply this data, this provides sufficient grounds for questioning the *'presumption of conformity'* with the Directives in question or for imposing sanctions.

In the case of products under the scope of the PPE, the technical documentation is one of the elements for carrying out an Attestation of Conformity with the involvement of a third party (Notified Body). In such cases, the EU type-examination certificate issued by a Notified Body also forms part of the technical documentation.

6.3 Form and content of the Technical documentation

The conformity assessment procedures are mainly intended to enable government bodies to make sure that the products placed on the market satisfy the statutory requirements. The manufacturer should be able to demonstrate by means of the technical documentation that the requirements are met.

The specific information that should be included in the technical documentation depends on the nature of the product and on the technical details needed to demonstrate that it conforms to either harmonised standards or the applicable essential requirements of the Directive. This should be indicated on a case-by-case basis, depending on the product. It is recommended that the technical documentation shall be organized as follows.

- a first part containing a list of essential technical data necessary for the conformity assessment inspection:

❖ General information according the PPE Regulation:

- the name and address of the manufacturer or his authorized representative;
- the PPE production plant in question,
- identification of the product (type, batch or serial number or other element allowing identification);
- a description of the product.
- Declaration of Conformity

❖ The manufacturer's technical documentation according annex III of the PPED:

(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.

- a second part, required particularly for Category III PPE, containing:

- all test reports;
- information concerning the quality manual;
- plans;
- description of the products and the manufacturing process;
- the quality management system standards applied

6.4 Availability of the Technical documentation

The technical documentation should always be kept available to the national authorities for inspection purposes and to Kiwa. The obligation to have at least one file of technical documentation available on the territory of the EEA commences when the product is placed on the market of the EEA, regardless of the product's geographical origin.

The obligation to keep the Technical documentation available rests with the manufacturer or his authorised representative established in the EEA.

If the manufacturer is not established in the EEA and has no authorised representative in the EEA, the obligation falls on the person (dealer or importer) who places the product on the market of the EEA.

The file should be kept for at least ten years after the date on which the product was last manufactured.

7 Markings

All products that are within the scope of the PPE are subject to CE marking according Article 30 of Regulation (EC) No 765/2008. The exact form and conditions are described in this section.

For products falling under the scope of the PPE it is prohibited to affix a CE marking before an EU Type-examination has been granted.

7.1 The CE marking

The affixing of a CE marking (Conformité Européenne) to products is an essential part of all *NLF Directives and Regulations*. If several Directives and or Regulations apply, the CE marking may, as a rule, be affixed only to products that comply with the conditions of all these Directives and or Regulations. When several Directives and or Regulatinos apply, the initials CE need to be affixed to the product only once.

The CE marking must satisfy the following criteria:

- The CE conformity marking shall consist of the initials "CE " taking the following form:

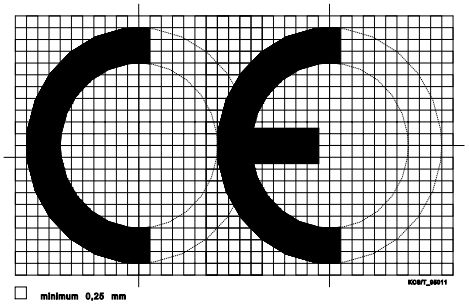

Figure 2: The initials CE.

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

Additional information in case of Category II and III

- The CE marking shall be followed by the last two digits of the year in which the CE marking was affixed. identification number of the body involved in the production control stage.

7.2 The CE marking with Kiwa as Notified Body, only Category III products

When Kiwa is involved as an Inspection Body the CE marking has to be as follows:

CE YY 0063

Figure 3: Example of the marking for the products

Annex A Abbreviations and paraphrases

Accredited laboratory
A laboratory operating in accordance with a quality standard, in this case ISO/IEC 17025 and is assessed by a recognized Accreditation Board.

Authorised representative
The person who, on the explicit (written) instructions of the manufacturer, acts on his behalf or for his account with respect to the obligations laid down in the Regulation.

EHSR
The Essential Health Safety Requirements are listed in Annex II of the PPE Regulation. These requirements define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so.

CE marking
A mark consisting of one or more symbols, indicating that the product in question conforms to all the applicable Directives.

Certificate holder
The person to whom a EU type-examination certificate is granted.

Certification
A procedure whereby a third party gives written assurance that a product, process or service conforms to specified requirements (ISO/IEC Guide 2: 1991).

Conformity assessment
Systematic examination of the extent to which a product, process or service satisfies further specified requirements (ISO/IEC Guide 2: 1991).

Declaration of Conformity
The Declaration of Conformity is a document drawn up by the manufacturer or its authorized representative. It should indicate that the product concerned complies with the standard(s) and Regulations and or Directive(s) to which the declaration refers.

DoC
Declaration of Conformity (DoC).

Dutch Council for Accreditation (RvA)
The Accreditation Body in The Netherlands in called Raad voor Accreditatie (in Dutch) or Dutch Council for Accreditation (in English).

EU type-examination procedure
A certification procedure whereby a Notified Body assesses the design, possibly by means of tests, of a representative specimen of the production envisaged.

EEA
The European Economic Area (EEA) comprises the 28 member states of the European Union plus Norway and Iceland.

ISO/IEC 17065
The standard for accreditation of certification bodies is ISO/IEC 17065.

Essential requirements
These are general criteria which products must satisfy before they may be placed on the market of the EEA. The essential requirements relate mainly to safety, health and the environment.

Harmonised standard
A harmonised standard is a standard published by the European Commission in the Official Journal of the European Union under the scope of a Directive. Compliance to a harmonised standard provides presumption of compliance to the essential requirements of the Directive.

Importer
Any person who places on the market of the EEA, a product from a third country.

Internal control of production
A conformity assessment procedure whereby the manufacturer assesses the design and production of his products himself.

ISO/IEC 17025
The standard for the accreditation of test laboratories in ISO/IEC 17025.

Kiwa
Notified Body under the PPE with identification number 0063.

Manufacturer
The person responsible for designing and manufacturing a product covered by a Directive with the view to placing it on the market of the EEA on his own behalf.

Nando
Nando is the website of the European Commission giving access to a database with all the designated and notified bodies under EU Directives.

Notified Body
A Notified Body is a third party authorised to carry out the tasks relating to approvals described in a European Directive. In general, a Notified Body can be regarded as a competent approvals body in a field where approval (certification) of a product is compulsory by law. A Notified Body is designated by the Member State of its establishment. A Member State of the EEA (European Economic Area) can only designate bodies falling within its sphere of competence.
Bodies designated by a Member State should satisfy criteria relating to proficiency, independence, impartiality, etc. In this connection, European standards EN45011 and EN45012 are particularly important. The body is then notified to the European Commission and the other Member States of the EEA and thereby acquires the status of the “Notified body”.

NVWA
Nederlandse Voedsel- en Warenauthoriteit

OEM products
An approval-holder may market the same product under different type designations and/or trademarks. One approval is issued for the product in which all the relevant type designations and/or trademarks are listed. (OEM = Original Equipment Manufacturer.)

Placing on the market
The first moment when a product, covered by a Regulation or Directive, being made available, for payment or free or charge, on the market of the EEA with a view to its distribution and/or use in the territory of the EEA.

PPE
Personal Protective Equipment

PPED
Personal Protective Equipment Directive 89/686/EEC

PPE Regulation
Personal Protective Equipment Regulation (EU) 2016/425

Raad voor Accreditatie
The Accreditation Body in The Netherlands in called Raad voor Accreditatie (in Dutch) or Dutch Council for Accreditation (in English).

Standard
A standard is a technical specification drawn up by a recognised standards organisation (CEN, CENELEC or ETSI) for repeated or continuous application, but with which compliance is not necessarily compulsory.

SZW
Ministerie of Sociale Zaken en Werkgelegenheid

Technical specification
A technical specification is the specification contained in a document which lays down the characteristics required of a product such as quality levels, performance, safety, dimensions, including the requirements applicable to the product as regards terminology, symbols, tests and test methods, packaging, marking and labelling.

Trademark
Trademark refers to the generic (brand) name under which a certain product is marketed.

Type designation
Type designation refers to the unique name under which a certain product is marketed.

VWS
Ministerie of Volksgezondheid, Welzijn en Sport

Annex B Model for the EU Type-examination

CERTIFICATE

EU type-examination certificate
(Module B)
<certificate number>

Issued	<date>	Date of expiration of validity	<certificate number>
Page	<Page> of <NumPages> This certificate has 1Hilbt Annexes.		

In compliance with the procedure specified in the **Personal Protective Equipment Scheme** RD_111, Kiwa Nederland B.V. declares as designated Notified Body with number 0063, that the stated products, evaluated according Annex 1 of this certificate, comply with the applicable essential health and safety requirements of the Personal Protective Equipment Regulation (EU) 2016/425, based on the applicable technical standards and specifications as listed in Annex 2 of this certificate.

Product description:	<xxx>
Trademark:	<xxx>
Type designation:	<xxx>
Size:	<xxx> / <xxx>
Variants:	See Annex 3

Manufacturer: <xxx>
Address: <xxx>
City: <xxx>
Country: <xxx>

This certificate is granted to:

Name:	<certificate holder>
Address:	
City:	
Country:	

PRODUCTS
RvA C 002

Ron Scheepers
Managing director

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https://www.kiwa.com/nl/en/market-areas/radio-wireless-and-electrical-equipment/

Chamber of commerce
08090048

Annex 1 to EU type-examination certificate <certificate number>

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General Conditions

- There is a presumption of conformity with respect to the requirements of the Personal Protective Equipment Regulation, when all applicable harmonized standards listed in the Official Journal of the EU are being applied.
- This EU Type-examination certificate is limited to the Personal Protective Equipment Regulation.
- This EU Type-examination certificate is part of the Conformity Assessment procedure Module B and C, as described in Personal Protective Equipment Regulation.
- The validity of this EU Type-examination certificate is limited to products, which are equal to the one(s) assessed for this EU Type-examination.
- When the manufacturer (or holder of this EU-type examination certificate) is placing the listed products on the European market or the countries of the EEA, he is obliged to label the products with the prescribed CE logo. The CE logo stands for conformity to all applicable Directives and Regulations. Next to the CE logo the manufacturer has to draw up and issue a Declaration of Conformity, declaring that the product(s) described in this EU Type-examination certificate, are in compliance with Regulation (EU) 2016/425 and any other applicable EU harmonization legislation.
- Each product shall be identified by means of type, batch and/or serial numbers and the name of the manufacturer and/or importer.
- If the equipment is to be modified, Kiwa shall be notified immediately. Depending on the modifications, Kiwa may have additional examinations carried out in consultation with the applicant.
- In case any referenced standard in this EU-type examination certificate is withdrawn or superseded and the presumption of conformity with the essential requirements has ceased, investigation by Kiwa is needed to determine the validity of this EU-type examination.
- For category III PPE, this certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19 of the Personal Protective Equipment Regulation.

Remarks and observations

The following conditions are applicable:

Annex 2 to EU Type-examination certificate <certificate number>

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Documentation lodged for this EU Type-examination

Test Reports:

Product Documentation:

Technical Standards and Specifications

The following standards have been used in full or part to cover the essential requirements:

Applied Standards

Annex C The Declaration of Conformity

It is recommended that declarations are drawn up on letter headed paper of the company and that original copies are forwarded to Kiwa together with the application in question. However, Kiwa can provide you with some generic declaration forms to complete.
According to the NLF a single EU DoC should be drafted, covering all applicable Regulations and Directives to the product.

EU Declaration of conformity

No.:

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

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: …

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:

7. Where applicable, the notified body … (name, number) … performed the EU type-examination (Module B) and issued the EU type-examination certificate … (reference to that certificate).

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

9. Additional information:

Signed for and on behalf of: …

(place and date of issue):
(name, function) (signature):

Model 1: The EU Declaration of conformity

Annex D Forms and documents

General
Several forms and documents are available to assist you in applying for product certification. The list below covers the most important documents relevant to the PPE.

RF_101 General Application form Personal Protective Equipment

RX_110 Quick reference guide PPE

Kiwa can provide you with original copies of these documents, but you may also use photocopies or printouts obtained from the website.

Annex E Additional information

For more information contact:

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