HORIZONTAL RECOMMENDATION FOR USE SHEETS (RfUs)
OF THE EUROPEAN COORDINATION OF NOTIFIED BODIES IN THE FIELD OF PPE
REGULATION (EU) 2016/425

Number of RfU PPE-R/	Version	Keywords	Approved by Horizontal Committee	Endorsed by PPE Working Group
00.004	01	Module C2 testing	30/03/17	23/01/18
00.005	01	Category III product	30/03/17	23/01/18
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00.052	01	Product marking, reference to standards	12/06/17	23/01/18
00.054	01	Modules C2 and D, non-conform product, unsafe design	12/06/17	23/01/18
00.055	01	Control systems	12/06/17	23/01/18

(1) : PPE-R/xx.xxx = Coordination of Notified Bodies/PPE-Regulation/Numbering of the RfUs

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.004 Version 1

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: VII Module C2	Clause:	

Key words:

Module C2 testing

Question:

When an EU Type Examination is based upon a withdrawn standard, should the C2 testing be conducted against the withdrawn standard or the current version?

Solution:

Whilst the type examination certificate remains valid, the C2 testing should be against the edition of the standard used as a basis to demonstrate conformity with the Regulation.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.005 Version 1

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Question related to	☒ PPE Regulation	☐ EN/prEN:	Other:
Article:	Annex: VII Module C2	Clause: 4.3	

Key words:

Category III product

Question:

If a PPE is classed as category III because the manufacturer claims one or more product features that qualify for category III, can the tests required under module C2 be limited to performance against this / these requirements?

Solution:

No. Once a PPE is claimed to meet performance requirements that qualify for category III, for whatever reason, the entire PPE item is classed as category III and not just single performance requirements.

There should be no difference in approach between all category III PPE with respect to deciding which performance requirements should be tested on C2 samples.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.010 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: VII Module C2 Clause: 4

Key words:

Sample selection / production address(es)

Question:

Certain tests cannot be performed on samples of finished PPE, but require that materials or components are tested.

In such cases, how shall samples of materials/components be obtained in order to satisfy the requirement for samples to be selected and appropriate tests carried out?

Solution:

Where samples are selected from the production plant, the required material/component samples are to be selected at the same time as the finished PPE, either from the company warehouse or production line.

Where samples are selected from the importer or similar, advance notice shall be given that materials and components will have to be made available for selection, and size and quantity requirements specified in advance of the C2 visit.

In addition to the planned testing (referring to the PPE properties) carry out some appropriate test suitable to confirm the identity of the supplied material or component samples with the material present in the PPE itself.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.013 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: VII Module C2 Clause:

Key words:

Sample selection / production address(es)

Question:

Module C2.3.a requires only the manufacturer's address to be specified. In many cases the production site(s) will not be the manufacturers address. How should this procedure cover the actual production sites?

Solution:

The application required under C2.3 shall also include the production site(s) if they are different from the manufacturer's address. The requirements of C2.4 shall apply to all production sites.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.014 Version 1

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: VIII Module D	Clause:	

Key words:

Module D: Suspension, withdrawal or restriction of certificates

Question:

What procedure should be followed in the event of failures during module D assessments?

Solution:

In the event of failures during module D assessments, the notified body concerned has to decide in each individual case, taking into account the reasons that lead to the failure and the risks involved.

In serious cases, e.g., major nonconformities issued against either the system or the product, the notified body should decide to either restrict, suspend or withdraw their module D approval; in that case other notified bodies and the Member State giving notification will have to be informed.

NOTE: The failures can concern both quality system failures and product performance failures. In the case of product failures, the module B notified body shall be informed.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.015 Version 1

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: VIII Module D	Clause:	

Key words:

Quality assurance system

Question:

Must existing certificates relating to QA-Systems (ISO 9001) be accepted by a notified body?

Solution:

No; but the notified body is able to take into account existing certificates relating to QA-systems (ISO 9001) if it is convinced of the qualification of the certification body (accreditation, mutual recognition and others). In all cases the notified body must add product and regulation-related aspects.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.025 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

testing of materials

Question:

Is it permissible to carry out tests on materials, parts or components identical to those comprising the PPE instead of carrying out tests on the PPE itself? If so, what are the conditions to be met for type-examination and for production control?

Solution:

It is possible to carry out tests on materials described in the standards with the sample taken either on the PPE itself or on a sample of the material if the manufacturer attests (in writing) that it is strictly identical to that used in the construction to the PPE and if the notified body can confirm the identity by examination of the reference PPE and the samples supplied. This procedure should be limited to a specific case as, for example, when referring to high cost PPE produced in small quantities.

The applicant has to supply one example of the PPE submitted to EU type-examination so that the notified body can check that the materials or items put forward for testing are indeed identical to those composing the PPE.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.027 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

components from different manufacturers

Question:

Should a notified body agree to issue an EU type-examination for a product submitted by manufacturer "A" which includes interchangeable components produced by a manufacturer "B" where the product requires to be tested as a complete device?

for example:

a) filters for an air powered device

b) chemical protective clothing without a hood and/or boots

c) helmet mounted ear muffs

Solution:

A notified body is responsible for reviewing the technical documentation for compliance with the relevant requirements of the Regulation. Provided the client's documentation submitted covers all the applicable requirements the notified body may perform or arrange for the necessary tests to be carried out and if found satisfactory issue an EU type-examination certificate.

Note: It is the manufacturer "A"'s responsibility to monitor that each subsequent product is in conformance with that tested for the EU type-examination and that the product manufactured by "B" remains the same and compatible with his tested product.

(see also RfUs 00.035 and 00.045, 00.046)

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.029 Version 1

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: II, 1.4	Clause:	

Key words:

use of pictograms

Question:

Is it possible to mark a product with a pictogram described in an EN standard when the verification of essential requirements has been made against another EN standard or other technical specification?

Solution:

It is possible to use the pictogram even if the standard used is not the EN standard where the pictogram is described.

The notified body, in reviewing the manufacturer's instructions for use (information supplied by the manufacturer), must ensure that the meaning of the pictogram is clearly defined in respect of the essential health and safety requirements of the PPE Regulation.

NOTE: 'Pictogram' refers to the pictorial presentation; this does not include the EN number or performance levels. These must not be used if the EN is not the basis for testing.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.030 Version 1

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Question related to ☐ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

test reports, designation of materials

Question:

In test reports, materials are often only referred to by a single, mostly commercial reference name. In many cases, however, this name covers a variety of materials different by structure and weight (for fabrics) or by origin and thickness (for leather).

Is it possible to have a uniform and clear "finger print designation" of materials in test reports in order to make an evaluation easier?

For this purpose, we propose to use the elements as given below:

- aramid twill 2/1 - 270 g/m²
- cow split 1.3 - 1.5 mm.

Solution:

A unique reference number or name identifying the material must be the same in the technical documentation and in the test report.

The technical documentation should contain a documentation of the material, i. e. a sample or a proper identification.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.031 Version 1

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Question related to ☐ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

Slip resistance, type examination certificate

Question:

Does slip resistance have to be considered an essential requirement for safety, protective and occupational footwear?

Solution:

Slip resistance is a general feature of safety, protective and occupational footwear.

Notified bodies have to carry out slip resistance testing, unless the manufacturer clearly claims in his product specification and in the user information that the footwear does not meet this requirement.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.036 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: 25 Annex: Clause:

Key words:

harmonised standards, essential requirements, EU type-examination

Question:

When carrying out an EU type-examination, what is the responsibility of the notified body when the applicable harmonised product standard does not address all the relevant essential health and safety requirements?

Solution:

Where a relevant harmonised product standard does not address all the relevant essential health and safety requirements the manufacturer must identify those not addressed in the standard and also state how these are dealt with in his technical documentation. The notified body is responsible for confirming that all the relevant essential health and safety requirements have been identified, listed and adequately dealt with when carrying out their review, inspection and testing for the EU type-examination.

Note 1: A harmonised product standard gives a presumption of conformity with those essential health and safety requirements which it identifies for the product and addresses.

Note 2: It must be remembered that the Regulation is the law and must be complied with whilst standards are one means by which a manufacturer may demonstrate his compliance with the Regulation's requirements.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.037 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

technical documentation

Question:

How should the notified body „verify“ that the model is the product described in the manufacturer’s technical documentation?

Solution:

The generally accepted action in order to verify that a PPE model has been produced in accordance with the manufacturer’s technical documentation is to conduct a visual comparison between an example of the model and a description of the model. The objective of the comparison is to ensure that, in general terms, the product is as described and that there are no obvious differences in general form or materials.

Note: The description of the model may take various forms, e. g. general assembly drawings, component drawings, photographs, material descriptions, etc.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.038 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: II, 1.2.1.1 Clause:

Key words:

innocuousness of PPE

Question:

What should notified bodies require from the manufacturer to demonstrate compliance with annex II, 1.2.1.1 ?

Solution:

Compliance may be demonstrated by a written declaration confirming that the submitted PPE does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health, if present; a list of these substances has to be submitted as part of the technical file. Tests as required by harmonised standards will not be affected.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.039 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

conformity to standard

Question:

Is it possible to certify a product in compliance with a standard where one or more requirements of the standard are not satisfied?

Solution:

No.

NOTE: The product may be certified in compliance with the essential health and safety requirements of the Regulation.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.040 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

CE marking, separate items of PPE, technical documentation

Question:

The manufacturer produces a range of products that can be used individually and in combination.

1. Is it possible to submit one technical documentation containing the designs etc. for all of these products?
2. In such a case, can each product separately bear the CE marking?

Solution:

1. It is possible to submit one technical documentation only for all products.
2. Yes, each product must be CE marked.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.047 Version 1

Number of pages: 2	Approval stage : Approved on :
Origin : Horizontal Committee	☐ C2 / D ad hoc group ☒ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

own brand certificates

Question:

How should applications for own brand certificates be dealt with?

Solution:

See attached

Own brand manufacturers type-examination certificates, Module B.

Any person / company / organisation placing a product on to the market in their own name is the manufacturer of that product within the terms of the PPE Regulation. It then follows that the manufacturer must make an application in their own name and be issued with certificates that support the CE marking of the PPE.

It is common practice for original manufacturers to offer their product to one or more companies who wish to sell the product as their own. There will be no identifiable link back to the original manufacturer in the market place.

The product offered for sale by the own brand manufacturer will be identical to the original product except for marking and probably user instructions. All other elements of the technical documentation can be applied to the own brand product.

The own brand manufacturer will be required to raise and sign a declaration of conformity before placing CE marked product on the market. This will include a statement covering modules C2 or D for category III PPE.

The own brand certificate will only remain valid while the cross-referenced original certificate remains valid.

As the own brand manufacturer is legally responsible for ensuring that the product(s) meet the requirements of the PPE Regulation, it is necessary for the minimum acceptable level of control and responsibilities to be established with the PPE notified bodies.

Proposed conditions to be fulfilled before the granting of certification for an own brand product: -

1. The original manufacturer to hold a valid type-examination certificate and if category III, to provide evidence of current supervision in line with module C2 or D.

2. Written agreement to be submitted, signed by both parties (original manufacturer and own brand manufacturer), covering the following:
   - Confirmation that the PPE subject to the current application is physically identical to product xxx, which is covered by type-examination certificate yyy.
   - Any difference between the original submission and this application to be listed.
   - Confirmation from the original manufacturer that only product fully compliant with type-examination certificate xxx will be supplied to own brand manufacturer yyy as the specified model.
   - Confirmation that the original manufacturer will advise the own brand manufacturer of any changes affecting the validity of either the type-examination certificate and for category III PPE, the supervision in line with module C2 or D.
   - Any proposed changes to the product will be sent to both the notified body and the own brand manufacturer before proceeding with the change.
   - Confirmation that the original technical documentation will be made available to the own brand manufacturer's notified body to support their application for certification and, for category III PPE, module C2 or D supervision.
   - Confirmation that both the original manufacturer and own brand manufacturer will inform each other of any incidents involving the products covered by the agreement

3. A copy of the EU type-examination certificate from the original manufacturer plus any documents that differ from the original technical documentation, e.g. marking and user information and access to the original technical documentation.

   The notified body should review the user information and labelling of the own brand manufacturer in order to confirm it meets the requirements of the PPE Regulation.

   A copy of the technical documentation amendments is then to be maintained by the own brand manufacturer and will be subject to review by the notified body during any ongoing surveillance activities.

4. For category III PPE, the notified body carrying out module C2 or D supervision will decide during the review of the own brand manufacturer's submission, activities etc., whether or not the premises of the own brand manufacturer need to be visited in the module C2 or D supervision.

5. The type-examination certificate issued to the own brand manufacturer will identify them as the manufacturer and will only reference the model identity as used by the own brand manufacturer. It is proposed that the original certificate does not need to be referenced on the certificate, but the NB holds this information, should it be required.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.048 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

sizing

Question:

A manufacturer declares sizes or size ranges for a PPE he submits for EU type-examination. What action does the notified body have to take?

Solution:

If a manufacturer submits a PPE for certification, declaring sizes or size ranges for the product, the notified body has to check whether the declared sizes are correct. The test report shall state the tested sizes or size ranges, and it is recommended that the certificate clearly states the approved sizes or size ranges.

PPE outside the size or size ranges covered by the EU type-examination must not be CE marked.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.049 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: III, V 3. (c), VII, 3. (a), VIII, 3. (a) Clause:

Key words:

traceability of technical documentation

Question:

What are the minimum criteria to guarantee the traceability / identification of documents within the technical documentation approved for an EU type examination certificate?

Solution:

In order to assure the notified body that carries out module C 2 or D procedures that the technical documentation as well as the model of the information supplied by the manufacturer, which are part of the technical documentation that must be presented by the manufacturer, correspond to the documents assessed during the EU type examination, the notified body that carries out the EU type examination will send back to the certificate holder at least a copy of the marking of the PPE and of the information supplied by the manufacturer. These documents must be dated and identified.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.050 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: V Clause:

Key words:

module C2 or D assessment, EU type-examination certificate

Question:

Should the notified body that carries out EU type-examination for a category III product check that module C2 or D assessment is present or in process?

Solution:

Yes.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.052 Version 1

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Question related to ☐ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: Clause:

Key words:

product marking; reference to standards

Question:

Is it allowed to use a defined term of a standard (e.g. FFP3) for marking a product without any reference to the standard?

Solution:

No.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.054 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: V, VII, VIII Clause:

Key words:

Modules C2 and D, non-conform product, unsafe design

Question:

What procedure should be followed during module C2 / D examinations in the event of a non-conforming product where the non-conformity is related to the design of that product?

Solution:

In the event of a non-conforming product where the non-conformity is related to the design of the product, the notified body doing the examination according to modules C2 or D has to inform the notified body who issued the corresponding EU type-examination certificate about this non-conformity.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.055 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Annex: V Clause:

Key words:

control systems

Question:

Which information shall be assessed during the EU type-examination if a control system is necessary to ensure a required protection of PPE?

Solution:

The manufacturer's technical documentation shall include detailed documentation based on his risk assessment covering e.g. the following:

- the specification of the safety function(s). These are functions of a control system which ensure a required protection (e.g. airflow, O_2 concentration, sound attenuation, light attenuation);
- the assessment and definition of the safety relevant parameters of the safety function (e.g. value of minimum airflow, value of min./max. O_2 concentration) ;
- the definition of the required performance level of the safety function. The definition shall cover the determination, verification and validation of the performance level (e.g. using the methods of EN ISO 13849-1 / IEC 62061, EN ISO 12100);
- the consideration of a possible loss or deviation of the necessary energy supply;

The manufacturer shall declare that he controls the adequacy and effectiveness of the control system. The notified body shall assess the technical documentation to verify the content accurately reflects the above requirements.

Note: Electronic and mechatronic components, so called control systems, may be used to ensure the required protection against risks of PP like e.g. electro-optical filters for welding, electronic hearing protection devices (HPD), powered filtering devices, self-contained breathing apparatus (SCBA) or self-contained re-breathing diving apparatus.