HORIZONTAL RECOMMENDATION FOR USE SHEETS (RfUs)
OF THE EUROPEAN COORDINATION OF NOTIFIED BODIES IN THE FIELD OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

REGULATION (EU) 2016/425

Number of RfU PPE-R/	Version	Keywords	Approved by Horizontal Committee	Endorsed by PPE Working Group
00.001	02	Product checks, time interval, random	30/05/18	22/04/19
00.002	03	Module C2, change of EC / EU type-examination certificate	30/05/18	22/04/19
00.003	03	Sample selection	30/05/18	22/04/19
00.004	01	Module C2 testing	30/03/17	23/01/18
00.005	01	Category III product	30/03/17	23/01/18
00.006	02	Retention of samples	30/05/18	22/04/19
00.008	03	Standard template for report content covering annual assessment process	30/05/18	22/04/19
00.009	03	Failure of C2 samples	30/05/18	22/04/19
00.010	01	Sample selection / production address(es)	30/03/17	23/01/18
00.011	03	C2 samples and process / production dormant	30/05/18	22/04/19
00.012	03	C2 samples / frequency of specific tests	30/05/18	22/04/19
00.013	01	Sample selection / production address(es)	30/03/17	23/01/18
00.014	01	Module D: Suspension, withdrawal or restriction of certificates	30/03/17	23/01/18
00.015	01	Quality assurance system	30/03/17	23/01/18
00.016	03	Re-assessment of approved quality systems	30/05/18	22/04/19
00.017	03	Module D minimum requirements	30/05/18	22/04/19
00.018	02	Module D minimum requirements	30/05/18	22/04/19
00.019	02	sub-contracting, accreditation, acceptance of test results, competence of laboratories	30/05/18	22/04/19
00.020	03	user information, conformity assessment	30/05/18	22/04/19
00.023	03	EU type-examination procedure, harmonised standards	30/05/18	22/04/19
00.024	03	standards, deficiencies	30/05/18	22/04/19
00.025	01	Testing of materials	12/06/17	23/01/18
00.026	03	identification of test samples	30/05/18	22/04/19
00.027	01	Components from different manufacturers	12/06/17	23/01/18
00.028	03	Marking, standard reference, testing according to prEN	30/05/18	22/04/19
00.029	01	Use of pictograms	12/06/17	23/01/18
00.030	01	Test reports, designation of materials	12/06/17	23/01/18
00.031	01	Slip resistance, type examination certificate	12/06/17	23/01/18
00.032	03	type-examination for category I PPE	30/05/18	22/04/19
00.034	02	information to users	30/05/18	22/04/19
00.035	03	interchangeable components, EU type-examination	30/05/18	22/04/19
00.036	01	Harmonised standards, essential requirements, EU type-examination	12/06/17	23/01/18
00.037	01	Technical documentation	12/06/17	23/01/18
00.038	01	Innocuousness of PPE	12/06/17	23/01/18
00.039	01	Conformity to standard	12/06/17	23/01/18
00.040	01	CE marking, separate items of PPE, technical documentation	12/06/17	23/01/18
00.041	02	information supplied by the manufacturer; sensitising or allergenic substances	30/05/18	22/04/19
00.043	02	uncertainty of measurement	30/05/18	22/04/19
00.044	03	dedicated test method standards	30/05/18	22/04/19
00.045	03	Article 3(1)(b); interchangeable components for equipment referred to in point (a) which are essential for its protective function	16/05/23	31/01/24

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00.046	03	interchangeable components	30/05/18	22/04/19
00.047	01	Own brand certificates	12/06/17	23/01/18
00.048	01	Sizing	12/06/17	23/01/18
00.049	01	Traceability of technical documentation	12/06/17	23/01/18
00.050	05	Module C2 or D assessment, EU type-examination certificate	22/11/23	26/05/24
00.052	01	Product marking, reference to standards	12/06/17	23/01/18
00.053	02	instructions for use	30/05/18	22/04/19
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
00.056	03	date of manufacture / obsolescence on the product marking	30/05/18	22/04/19
00.058	03	EU type-examination certificate / re-certification / transitional period	30/05/18	22/04/19
00.061	02	Risk assessment	30/05/18	22/04/19
00.069	04	Issues relating to negative conformity assessment results / refused / withdrawn / suspended / restricted	22/11/23	26/05/24
00.072	2	Test method standards, dated, undated	16/05/23	31/01/25
00.075	01	Renewal date, renewal, review, simplified review	22/11/23	26/05/24

(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/00.001 Version 2

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Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: VII Module C2	Clause: 4.2	

Key words:

Product checks, time interval, random

Question:

What does "random" mean in module C2, 4.2?

Solution:

For on-site assessments and sampling, the interval between visits to be varied, and for remote sampling selection without the manufacturer's advance knowledge, where possible. Where samples are to be selected from distributors, warehouses etc. it will be necessary to arrange visits directly with the people concerned.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.002 Version 3

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

Key words:

Module C2, change of EC / EU type-examination certificate

Question:

When controls carried out in accordance with module C2 give performance level classification figures lower than those stated in the EC / EU type-examination certification, should the original EC / EU type-examination certificate be changed?

Solution:

Yes; either the original certificate is amended or a new certificate issued, and the model reference is changed.

The procedure set out in 4.4 and 4.6 should be followed.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.003 Version 3

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

Article: Annex: VII Module C2 Clause:

Key words:

Sample selection

Question:

What is the minimum requirement to be applied to the method of obtaining samples for testing under module C2?

Solution:

As a minimum, the notified body or an independent representative of the notified body, shall visit a location agreed with the manufacturer (manufacturing site, importer, distributor, retail outlet), and shall randomly select the samples from the available stock.

	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/00.006 Version 2

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

Article: Annex: V and VII Clause:
Modules B and C2

Key words:

Retention of samples

Question:

Is there any requirement in the PPE Regulation for notified bodies to retain samples of the equipment that they have type-examined (Module B) or tested during the annual control of the final product (Module C2)?

Solution:

No.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.008 Version 3

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

Key words:

Standard template for report content covering annual assessment process

Question:

What are the minimum requirements for the report content when implementing Recommendation for Use sheet 00.007?

NOTE:

RfU 00.007 clearly specifies that 2 separate activities are required when assessing module C2, namely: -

1) Annual selection of samples to confirm continued compliance with the reference standard / specification and the type-examined

AND

2) Annual assessment of the production control to determine any evidence of non-homogeneity.

Solution:

See attached pages 2 and 3

Confidential **Report number and date:**

Module C2 Annual Surveillance Report

Notified Body – name / address / number:

Certificate holder: **Period covered by report:**

General Reference Documents:

Recommendation for use sheet, 00.007. PPE Regulation 2016/425/EU, Module C2

EU type-examination certificate numbers covered by the surveillance:

Harmonised standards / technical specifications within the scope of the surveillance:

A. Annual assessment of product compliance with standard / specification and type-examined, reference 2A of RfU 00.007

1. Location(s) visited and dates:

2a. Selection carried out by…….. Relationship to notified body…….

2b. Company representative, name and position……

2c. Relationship of company visited to type-examination certificate holder

Certificate Holder Production site Importer Secondary production site
Distributor Retail Outlet European office of same company
Other (please specify)

List of PPE
- available
- not available
- not selected
- selected plus lot / batch numbers

3. Attached reference documents

Visit report, number xxxxxxx **Test report, number yyyyyyy**

4. Sample selection was positive / negative. Product testing was positive / negative

5. Sample selection and testing demonstrated compliance with the reference specification / standard and type-examined, yes / no.

B. Annual assessment of production not being homogeneous, reference 2B of RfU 00.007

1. Method employed to perform assessment, please specify:

2B(i) - On-site review of production and test records.
2B(ii) - On-site audit of production control.
2B(iii) - Production non-homogeneity assessed by selection of a single, large sample.
2B(iv) - Production non-homogeneity assessed by assessment of samples throughout the year.

2a. Assessment(s) carried by …… Relationship to notified body. ……..

2b. Company representative, name and position……

Confidential **Report number and date:**

Module C2 Annual Surveillance Report

3. Attached reference documents.

Visit report(s), number xxxxxxx Test report(s), number yyyyyyyy

4. According to our judgement, the assessment concluded that production was not homogeneous, yes / no.

Justification of nonconformities

Conclusion of notified body:

Overall conclusion of the annual surveillance, positive / negative.

Signature…….. Name and position …….. Date ……..

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.009 Version 3

Number of pages: 1	Approval stage : Approved on :
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Question related to	☒ PPE Regulation	☐ EN/prEN:	☒ Other:
Article:	Annex: VII Module C2	Clause: 2B(iv)	RfU sheet 00.007, 2B(iii) and

Key words:

Failure of C2 samples

Question:

What are the necessary actions following failures when samples are taken as required by recommendation for use sheet 00.007, sections 2B(iii) and 2B(iv), assessment of non-homogeneity?

Solution:

The following steps should be taken:

1. Manufacturer asked to investigate the failure(s) and advise the notified body of their findings.
2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how.
3. Notified body to then determine what level of additional testing is required
4. Additional samples requested from the manufacturer and tested under the authority of the notified body
5. If additional samples pass the required testing, C2 considered completed.
6. If additional samples fail, steps 1 to 4 repeated.
7. If second set of additional samples fail, C2 certification to be withdrawn / not re-issued.

NOTE:

1. If the module C2 body is not the module B body, module B body to be kept informed throughout the process.
2. Notifying authorities to be informed of failures.

	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/00.011 Version 3

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☒ Other:
Article:	Annex: VII Module C2	Clause:	RfU sheet 00.007, 2B(iii) and 2B(iv)

Key words:

C2 samples and process / production dormant

Question:

What are the necessary actions where a company follows module C2 and production is dormant for a period, resulting in module C2 not being able to be carried out?

Solution:

1. C2 approval is covered by a separate report or certificate with a 1 year validity.

2. Where the C2 approval does not have a validity period.

Either:
C2 supervision / sampling cannot be carried out due to no production, certificate remains valid and C2 process is activated when production starts or restarts, manufacturer to inform NB. C2 process to be satisfactorily completed before product is allowed to be placed on the market.

Or:
C2 supervision / sampling cannot be carried out due to no production, certificate remains valid and C2 process is activated when production starts or restarts, manufacturer to inform NB. Product is allowed to be placed on the market while the C2 assessment is organised / carried out.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.012 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Key words:

C2 samples / frequency of specific tests

Question:

Is it acceptable for some of the required C2 tests to be carried out once every two or three years instead of every year?

Solution:

Yes, provided that the principle has been discussed and agreed by the applicable vertical group, and the tests that this principle could apply to have been specified by the vertical group.

	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/00.016 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : C2D Ad hoc group	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Key words:

Re-assessment of approved quality systems

Question:

Shall approved quality systems be re-assessed?

Solution:

Yes, at a recommended frequency of every third year, with surveillance audits being carried out once per 12 month period following issue of approval.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.017 Version 3

Number of pages: 5	Approval stage : Approved on :
Origin : Horizontal Committee, C2D Ad hoc group	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to	☒ PPE Regulation	☐ EN/prEN:	☒ Other:
Article:	Annex: VIII Module D	Clause:	ISO 9001:2008

Key words:

Module D minimum requirements

Question:

What are the minimum requirements that systems based upon ISO9001 2008 complying with module D have to cover?

Solution:

The minimum requirements are as attached pages, 2 to 5.

The system shall be documented in the form of a manual, procedures and supporting work instructions or similar. The scope of the system shall be specified.

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.

The system requirements are limited to category III PPE, CE marked under the PPE Regulation (EU) 2016/425

Heading, with reference to ISO9001:2008	Comments
4 Quality management system **4.1 General requirements** Comply with Clause 4.1 of ISO 9001:2008 The quality system ensures compliance of the product with the product described in the EC / EU type-examination certificate(s). System shall be documented in the form of manuals, procedures and work instructions.	Shall include or reference quality objectives. Clear identification and control mechanisms for any outsourced processes to be documented, especially applicable where the company does not manufacture the PPE. Cross reference clause 7.4.1
4.2 Documentation requirements Comply with Clause 4.2 of ISO 9001:2008 **4.2.1 General** Complies with Clause 4.2.1 of ISO 9001:2008 **4.2.2 Quality manual** Complies with Clause 4.2.2 of ISO 9001 :2008 **4.2.3 Control of documents** Complies with Clause 4.2.3 of ISO 9001:2008	To include technical file documents, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards.
4.2.4 Control of quality records Complies with Clause 4.2.4 of ISO 9001:2008 At least the following documents are retained for at least 10 years after supply of the last item: Those arising from regulatory requirements, to include module D.6 (a) the documentation referred to in point 3.1 of module D (b) the information related to the change referred to in point 3.5 of module D (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4 of module D Declaration of conformity, 5.2 module D Training records Inspection and test data Calibration data	Retention period to clearly specify period after supply of the last production item.
5 Management responsibility **5.1 Management commitment** Complies with Clause 5.1 of ISO 9001 :2008	
5.3 Quality policy Complies with Clause 5.3 of ISO 9001:2008	
5.4 Planning **5.4.1 Quality objectives** Complies with Clause 5.4.1 of ISO 9001:2008	

5.4.2 Quality planning Complies with Clause 5.4.2 of ISO 9001:2008 The quality system ensures compliance of the product with the EC / EU type-examination certificate(s) All adopted elements, requirements and provisions are documented in a systematic and orderly manner in the form of written policies, procedures and instruction.	
5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Complies with Clause 5.5.1 of ISO 9001:2008 The following shall be defined: A. Need to liaise with notified body responsible for the EC / EU type-examination in case of changes to the design defined in the EC / EU type-examination certificate and the technical documentation B. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes of quality system. C. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes made to the product or technical file **5.5.2 Management representative** Complies with Clause 5.5.2 of ISO 9001 :2008 **5.5.3 Internal communication** Complies with Clause 5.5.3 of ISO 9001:2008	Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.
5.6 Management review **5.6.1 General** Complies with Clause 5.6.1 of ISO 9001:2008 A. Intervals should be at least every 12 months, but with a maximum of 14 months B. Top management chairs the review C. The authorized person(s) participate(s) in the review **5.6.2 Review input** Complies with Clause 5.6.2 of ISO 9001:2008 **5.6.3 Review output** Complies with Clause 5.6.3 of ISO 9001 :2008	The review and audit systems must include those departments / positions responsible for compliance with the PPE Regulation.
6 Resource management **6.1 Provision of resources** Complies with Clause 6.1 of ISO 9001 :2008 **6.2 Human resources** **6.2.1 General** Complies with Clause 6.2.1 of ISO 9001:2008 **6.2.2.Competence, awareness and training** Complies with Clause 6,2.2 of ISO 9001 :2008 **6.3 Infrastructure** Complies with Clause 6.3 of ISO 9001 :2008 **6.4 Work environment** Complies with Clause 6.4 of ISO 9001 :2008	To include all personnel involved in those system elements covered by these requirements.

7 Product realization **7.1 Planning of product realization** Complies with Clause 7.1 of ISO 9001:2008	
7.4 Purchasing. **7.4.1 Purchasing process** Complies with Clause 7.4.1 of ISO 9001:2008 Where the processes of manufacture, tests and final inspection are sub-contracted the following shall apply: (the responsibility to ensure compliance to specific requirements cannot be sub-contracted) A. Subcontractor has been selected after an evaluation has demonstrated the capability of ensuring compliance with all specific requirements B. The evaluation has been performed by one of the following methods; - third party quality system certification - documented evaluation which provides objective evidence of the capabilities - documented site assessment to ensure all relevant capabilities C. Where the features affecting the type of protection cannot be verified at a later stage, the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure that relevant controls are available, documented, understood and effective D. Suppliers not used for a period of one year are re-evaluated prior to placing of the contract E. Ability of supplier is reviewed at least once a year	The Notified Body is responsible for ensuring that the manufacturer's quality system complies with module D requirements, and this may include on-site audits of any sub-contracted activities which potentially impact upon conformity with the EC / EU type-examination and / or module D.
7.4.2 Purchasing information Complies with Clause 7.4.2 of ISO 9001:2008 **7.4.3 Verification of purchased products** Complies with Clause 7.4.3 of ISO 9001:2008 A. Verification arrangements are implemented if purchased product can compromise the type of protection B. Routine tests or inspections confirmed with declaration of conformity.	
7.5 Production and service operations **7.5.1 Control of production and service provision** Complies with Clause 7.5.1 of ISO 9001:2008 Requirements contained in the EC / EU type-examination Certificates are considered. **7.5.2 Validation of processes for production and service provision** Complies with Clause 7.5.2 of ISO 9001:2008 **7.5.3 Identification and traceability** Complies with Clause 7.5.3 of ISO 9001:2008 Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained **7.5.4 Customer property** Complies with Clause 7.5.4 of ISO 9001:2008 **7.5.5 Preservation of product** Complies with Clause 7.5.5 of ISO 9001 :2008	Traceability is not required. Identification of product is required to cover type, batch or serial number, reference Article 8.5

7.6 Control of measuring and monitoring devices Complies with Clause 7,6 of ISO 9001 :2008 If the certificate of the calibrated instrument does not bear the accreditation logo of a national authority then the certificate shall contain the following: -an unambiguous identification of the item calibrated -traceability to (inter)national standards -the method of calibration -a statement of compliance with any relevant specification -the calibration results -the uncertainty of measurement, where relevant -the environmental conditions, where relevant -the date of calibration -the signature of the person under whose authority the certificate was issued -the name and address of issuing organization and the date of the certificate -a unique identification of the calibration certificate	
8 Measurement, analyses and improvement **8.1 General** Complies with Clause 8.1 of ISO 9001:2008	
8.2 Measuring and monitoring **8.2.2 Internal audit** Complies with Clause 8.2.2 of ISO 9001:2008 The audit program addresses the effectiveness of the elements of the quality system described in this standard. The audits should be carried out at least every 12 months, but within a maximum of 14 months **8.2.3 Monitoring and measurement of processes** Complies with Clause 8.2.3 of ISO 9001:2008 **8.2.4 Measurement and monitoring of product** Complies with Clause 8.2.4 of ISO 9001 :2008 The system shall include inspection and testing from purchased material to finished product, to the extent necessary to demonstrate continued compliance with the type-examined and the reference product specification, normally a standard. These activities shall be carried out by the manufacturer on a regular basis and shall be linked to production volumes, time or both. To include correct marking of the product, including the CE marking format and user information to include NB details.	
8.3 Control of nonconformity Complies with Clause 8.3 of ISO 9001 :2008 a) There shall be a system for the customer to be identified b) The manufacturer takes action if nonconforming product has been supplied to a customer c) In case of b) the manufacturer informs the customer and the Notified Body responsible for module D supervision. d) In case of b) and the nature of the nonconformity could affect user protection, and if not possible to trace the product, then additional actions shall be taken to inform the users, for example, notices placed in appropriate publications e) Product concessions that could affect user safety are not permitted. All concessions to be documented and authorised.	
8.4 Analyses of data Complies with Clause 8.4 of ISO 9001:2008	
8.5 Improvement **8.5.2 / 8.5.3 Corrective action / Preventive action** Complies with Clause 8.5.2 of ISO 9001:2008	To include customer complaints, warranty returns and returned products

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.018 Version 2

Number of pages: 5	Approval stage : Approved on :
Origin : Horizontal Committee, C2D Ad hoc group	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to	☒ PPE Regulation		☐ EN/prEN:	☒ Other:	
Article:	Annex: VIII Module D		Clause:	ISO 9001:2015	

Key words:

Module D minimum requirements

Question:

What are the minimum requirements that systems based upon ISO9001 2015 complying with module D have to cover??

Solution:

The minimum requirements are as attached pages, 2 to 5.

ISO 9001:2015 Applicability to Module D PPE Regulation

The system shall be documented in the form of a manual, procedures and supporting work instructions or similar. The scope of the system shall be specified.

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.

The system requirements are limited to category III PPE, CE marked under the PPE Regulation (EU) 2016/425

ISO 9001 2015 clause reference. General compliance plus any specific requirements	Comments / Notes
4.4 Quality management system and its processes	System shall be documented in the form of manuals, procedures and work instructions.
5 Leadership (Section title)	
5.1 Leadership and commitment	
5.2 Policy	
5.3 Organizational roles, responsibilities and authorities The following shall be defined: A. Need to liaise with notified body responsible for the EU type-examination in case of changes to the design defined in the EU-type examination certificate and the technical documentation B. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes of quality system. C. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes made to the product or technical file	Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.
6 Planning (Section title)	
6.2 Quality objectives and planning to achieve them	
6.3 Planning of changes	
7 Support (Section title)	
7.1 Resources	
7.1.1 General	
7.1.2 People	To include all personnel involved in those system elements covered by these requirements.
7.1.3 Infrastructure	
7.1.4 Environment for the operation of processes	

7.1.5 Monitoring and measuring resources If the certificate of the calibrated instrument does not bear the accreditation logo of a national authority then the certificate shall contain the following: -an unambiguous identification of the item calibrated -traceability to (inter)national standards -the method of calibration -a statement of compliance with any relevant specification -the calibration results -the uncertainty of measurement, where relevant -the environmental conditions, where relevant -the date of calibration -the signature of the person under whose authority the certificate was issued -the name and address of issuing organization and the date of the certificate -a unique identification of the calibration certificate	
7.2 Competence	
7.3 Awareness	
7.4 Communication	
7.5 Documented Information	To include technical documentation, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards. Retention period to clearly specify period after supply of the last production item. Items 2, 3, 4 to be held for 10 years relative to each production lot / batch.
7.5.1 General	
7.5.2 Creating and Updating	
7.5.3 Control of Documented Information At least the following documents are retained for at least 10 years after supply of the last item: 1.Those arising from regulatory requirements, to include module D.6 (a) the documentation referred to in point 3.1 of module D (b) the information related to the change referred to in point 3.5 of module D (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4 of module D Declaration of conformity, 5.2 module D 2. Training records 3. Inspection and test data 4. Calibration data	
8 Operation (Section title)	
8.1 Operational planning and control	

8.4 Control of externally provided processes, products and services If manufacture, tests and / or final inspection is sub-contracted the responsibility to ensure compliance to specific requirements cannot be sub-contracted. Controls to be applied where manufacture or testing or inspection is subcontracted: A. Subcontractor has been selected after an evaluation has demonstrated the capability of ensuring compliance with all specific requirements B. The evaluation has been performed by one of the following methods; - third party quality system certification - documented evaluation which provides objective evidence of the capabilities - documented site assessment to ensure all relevant capabilities C. Where the features affecting the type of protection cannot be verified at a later stage, the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure that relevant controls are available, documented, understood and effective D. Suppliers not used for a period of one year are re-evaluated prior to placing of the contract E. Ability of supplier is reviewed at least once a year	The Notified Body is responsible for ensuring that the manufacturer's quality system complies with Module D requirements, and this may include on-site assessment of any subcontracted activities which potentially impact upon conformity with the EU type-examination and / or Module D.
8.4.1 General	
8.4.2 Type and extent of control	A. Verification arrangements are implemented if purchased product can compromise the type of protection B. Routine tests or inspections confirmed with declaration of conformity.
8.4.3 Information for external providers	
8.5 Production and service provision	
8.5.1 Control of production and service provision	
8.5.2 Identification and traceability Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained	Traceability is not required. Identification of product is required to cover type, batch or serial number, reference Article 8.5
8.5.3 Property belonging to customers or external providers	
8.5.4 Preservation	
8.5.5 Post-delivery activities	
8.5.6 Control of changes	
8.6 Release of products and services	
8.7 Control of nonconforming outputs	

9 Performance evaluation (Section title)	
9.1 Monitoring, measurement, analysis and evaluation The system shall include inspection and testing from purchased material to finished product, to the extent necessary to demonstrate continued compliance with the type-examined and the reference product specification, normally a standard. These activities shall be carried out by the manufacturer on a regular basis and shall be linked to production volumes, time or both. To include correct marking of the product, including the CE marking format and user information to include NB details.	
9.1.1 General	
9.1.3 Analysis and evaluation	
9.2 Internal audit The audit program addresses the effectiveness of the elements of the quality system described in this standard. The audits should be carried out at least every 12 months, but within a maximum of 14 months	
9.3 Management review A. Intervals should be at least every 12 months, but with a maximum of 14 months B. Top management chairs the review C. The authorized person(s) participate(s) in the review	The review and audit systems must include those departments / positions responsible for compliance with the PPE Regulation.
10 Improvement (Section title)	
10.1 General	
10.2 Nonconformity and Corrective Action a) There shall be a system for the customer to be identified b) The manufacturer takes action if nonconforming product has been supplied to a customer c) In case of b) the manufacturer informs the customer and the Notified Body responsible for module D supervision. d) In case of b) and the nature of the nonconformity could affect user protection, and if not possible to trace the product, then additional actions shall be taken to inform the users, for example, notices placed in appropriate publications e) Product concessions that could affect user safety are not permitted. All concessions to be documented and authorised.	To include customer complaints, warranty returns and returned products.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.019 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: 26 Annex: Clause:

Key words:

sub-contracting, accreditation, acceptance of test results, competence of laboratories

Question:

Is it possible for a certification body to accept test data obtained by other than accredited laboratories?

Are test reports from authorities outside the European Union acceptable for the purpose of CE marking?

If this is so, what are the minimum criteria to be used in judging their competency and how should they be monitored?

What quality control methods should be applied to sub-contracting laboratories?

Can the notified body use test reports on materials, items or components carried out by other specialised laboratories?

Can the notified body use reports on tests carried out by the manufacturer or the applicant?

Solution:

Under all circumstances, the notified body takes on the responsibility for test results/test reports it accepts as the basis for certification.

Therefore, it should generally be recommended to use test results from accredited test laboratories only.

As this will not always be possible, other sources of testing have to be used. Sub-contracting laboratories should meet the requirements according to ISO / IEC 17025, if this is not the case, the notified body has to ensure by other means that the test results are reliable.

The notified body itself will have to specify the conditions for the acceptance of other test laboratories to carry out the tests. It shall ensure that the sub-contractor meets the requirements set out in Article 26 of the PPE Regulation.

Quality control measures for sub-contracting test laboratories are important, the notified body itself is responsible for deciding how to proceed with this.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.020 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: III, k Clause:

Key words:

user information, conformity assessment

Question:

What language version of the user information will be assessed in the framework of conformity assessment, when notified bodies carry out certification procedures for foreign manufacturers?

Solution:

The notified body can choose which languages it does accept for assessing. Any translation is the responsibility of the manufacturer / authorised representative. It would be useful, however, to note in the test report which language version was checked.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.023 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: III, g; V, 4f	Clause:	

Key words:

EU type-examination procedure, harmonised standards

Question:

What is the procedure to be applied to the EU type-examination in the absence of approved harmonised standards covering product requirements and / or test methods?

Solution:

The notified body has to decide what will be the basis for testing against the requirements of the PPE Regulation.

The manufacturer has to set the specification for the product and ask for certification against this specification. Under normal circumstances, the specifications of the manufacturer will remain strictly confidential.

The notified body is responsible for assessing whether or not the specification meets the applicable requirements of annex II and determining whether or not the submitted PPE does comply with the requirements.

It is recommended to refer to existing standards (e.g. national or ISO (international)) whenever possible.

If this is not possible, the notified body should identify the objectives to be reached in testing for conformity with the requirements and specify test procedures appropriate for the EU type-examination.

The proposed method may be discussed with the other notified bodies if this is necessary. If there is a general interest in a harmonization of the test procedure, the subject should be brought into the European standardisation committee responsible.

Note: The references of technical specifications must be included in the EU type-examination certificate and EU declaration of conformity.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.024 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

standards, deficiencies

Question:

What action should be taken if deficiencies or mistakes in standards are detected?

Solution:

Deficiencies and mistakes in standards always have to be discussed in the relevant CEN or CENELEC TC or WG. Therefore, as soon as any such mistake is recognised, the appropriate body has to be informed and asked to take action for a possible revision of the standard as soon as possible.

In addition to that, the problem should be discussed within the vertical group so that a general approach to the problem is laid down and the notified bodies can agree how to proceed with the testing before a revision of the standard is published. The relevant TC or WG should be informed of any such interim solution.

If the problem is of general interest, the Horizontal Committee should be informed so that the subject can be discussed at Horizontal Committee level and, if necessary, with the relevant CEN or CENELEC authorities.

The European Commission will receive the existing Recommendation for Use sheets for approval.

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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/00.026 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

identification of test samples

Question:

What measures should be adopted to ensure traceability and identification of specific PPE product to the original type?

Solution:

There must be no ambiguity regarding the identification of the PPE having been submitted as a type (model) to a notified body for EU type-examination.

PPE placed on the market are the subject of the tested type declaration of conformity.

The following is recommended:

- the alphanumeric reference of the models must be provided by the manufacturer with an indication of its meaning
- the photographs needed for correct identification of the PPE must accompany the certificate and a copy of these photographs must be archived with the file by the notified body
- an example of the PPE model can be archived by the notified body when this is possible.

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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/00.028 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

Marking, standard reference, testing according to prEN

Question:

If only a prEN is available at the time of EU type-examination, can the product be marked with the standard number „EN ...“?

When a product is marked with a prEN, can EN be marked on the product, once the standard is ratified?

Solution:

Marking with a standard reference is not mandatory by the PPE Regulation.

Where a manufacturer decides to mark a standard or prEN on his product, the following principles apply:

As long as no final standard exists or the final standard is not identical with the prEN, the marking cannot be "EN ...".

If the ratified EN is identical to the prEN, then „EN ...“ may be marked on the product, subject to confirmation by the notified body.

Where the ratified EN is not identical to the prEN, then „EN ...“ cannot be marked on the product.

Marking with a prEN is not recommended. However, where a manufacturer decides to mark with the prEN used for the EU type-examination then it should be fully identified by year and/or issue.

Note: As long as a prEN or EN do not give presumption of conformity, conformity assessment has to be based on a technical specification (Annex III of the PPE Regulation).

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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/00.032 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

type-examination for category I PPE

Question:

Could PPE which do not belong to categories II or III be submitted to an EU type-examination on a voluntary basis?

Solution:

No, only PPE belonging to categories II or III can be submitted to an EU type-examination procedure leading to the issue of an EU type-examination certificate.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.034 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: II, 1.4 Clause:

Key words:

information to users

Question:

What is the responsibility of the notified body in checking the information to users?

Solution:

The notified body shall verify that the equipment can be used in complete safety for its intended purpose. In order to do this, the notified body shall check that the claims of the manufacturer on the area and limits of protection of the product are in line with the technical specification used and with the relevant essential safety requirements. One of the essential safety requirements is to supply all relevant information as required by annex II, clauses 1.4, 2 and 3. The notified body must check that the information is given in accordance with these requirements and that it does not contain misleading statements and obvious mistakes concerning the protection provided. The manufacturer has the final responsibility for the accuracy of the content including translations.

Note : Claims of compliance with standards other than harmonised European standards that have the same scope as those used as a basis for type-examination or claims that are not related to user protection, e.g. value for money etc., are the sole responsibility of the manufacturer.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.035 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: 3 (1) (b) Annex: Clause:

Key words:

interchangeable components, EU type-examination

Question:

Should interchangeable components be subject to a separate EU type-examination?

Solution:

Yes, an EU type-examination certificate must be issued in accordance with Article 3 (1) (b).

The notified body shall carry out sufficient evaluation and/or testing to verify their suitability for the stated equipment in its final assembly.

(See also RfUs 00.027, 00.045, 00.046)

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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/00.041 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: II, 1.2.1.1 Clause:

Key words:

information supplied by the manufacturer; sensitising or allergenic substances

Question:

Should the manufacturer of PPE display all substances with sensitising or allergenic potential in the "information supplied by the manufacturer", if the PPE is designed to get (even if only partly) in close skin contact with the user, or if parts of the PPE may be released and taken up via the inhalation route by the user?

Solution:

Yes. Annex II, 1.2.1.1 (suitable constituent materials) requires that "PPE materials and parts, including any of their decomposition products must not adversely affect user hygiene or health".

In case that PPE contains substances which are known to be potentially sensitising or allergenic, the manufacturer has to display each individual relevant substance in the information supplied by the manufacturer to give a warning to all potentially concerned users.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.043 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to ☐ PPE Regulation ☒ EN/prEN: 17025 ☐ Other:

Article: Annex: Clause: 5.10.3.1 c)

Key words:

uncertainty of measurement

Question:

When notified bodies commission testing on test laboratories complying with EN/ISO/IEC 17025, and the reference specification includes pass / fail criteria, does the notified body have to make a specific request for uncertainty of measurement to be included in the test report?

Solution:

No.

EN/ISO/IEC 17025 includes a clear requirement for uncertainties of measurement to be available and reported where the uncertainty might affect compliance with pass / fail criteria. In such cases, the test laboratory has to include the uncertainty.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.044 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

dedicated test method standards

Question:

Product standards often refer to specific standards or other sources for the specification of test methods. Changes in the test method can result in differences with regard to the interpretation of test results for the assessment of the product, e.g. with regard to performance levels.

What should notified bodies do when a test method standard is revised?

Solution:

As long as the product standard has not been revised and there is an undated reference in the standard, the latest version of the test method has to be used.

NOTE: If a test method standard has been revised, the consequences for the interpretation of test results should be discussed in the PPE notified body coordination group and an amendment to the product standard be proposed as quickly as possible, if necessary.

	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.045 Version 03

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 16/05/2023 ☒ EU PPE Expert Group 31/01/2024

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

Article: : 3 (1) (b) Annex: Clause:

Key words:

Article 3(1)(b); interchangeable components for equipment referred to in point (a) which are essential for its protective function

Question:

Who can apply for EU type-examination of interchangeable components in the meaning of Article 3, (1) (b) of the PPE Regulation?

Solution:

The situation will depend on the PPE presented. Some performance standards have design restrictions that present a common/standardised approach (e.g. EN 148-1 "Respiratory protective devices - Threads for facepieces - Part 1: Standard thread connection) - such that the PPE continues to perform provided each Manufacturer produces in conformity with the standard. So therefore, any applicant may apply.

Where no such standard exists, the Notified Body must assess the risk of a change by one manufacturer, on the potential conformity of the second manufacturer proposing an interchangeable part. In this case the manufacturer of the interchangeable component must ensure it is identical to the manufacturer's original components in safety performance, and there must be a contractual agreement between them, which authorises the manufacturer of the interchangeable component.

(see also RfU 00.027, 00.035, 00.046)

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.046 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article: 3 (1) (b)	Annex:	Clause:	

Key words:

interchangeable components

Question:

Do interchangeable components of protective equipment that was placed on the market before the PPE Directive became effective fall under the scope of the PPE Regulation?

Solution:

Even if the original equipment is not CE marked, such interchangeable components fall under the scope of the PPE Regulation.

The suitability of the component for the intended use of the PPE in the protective equipment must be assessed and certified. The notified body must have access to the complete documentation concerning the whole equipment (test reports and certificates, if existing).

A simple certificate confirming equivalence with the part to be replaced is not enough.

	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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

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 05

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 22/11/2023 ☒ EU PPE Expert Group 26/05/2024

Question related to ☒ PPE Regulation ☐ PPE Guidelines ☐ 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 initial EU-type-examination for a category III product check that module C2 or D assessment is present or in process?

Solution:

No.

In the regulation it is the manufacturer's responsibility to comply with all requirements before placing product on the market, and therefore they can decide upon the timing of applying for modules B and C2/D.

Where a C2 / D agreement is not in place, manufacturers should have a place marker for their labels and declaration, e.g. NB XXXX.

The module B notified body approving the general presentation and content of conformity marking does not convey that a manufacturer has the right to use any notified body number shown.

It shall be understood that the place marker 'NB XXXX' cannot be used to place product on the market, and that the manufacturer shall take action to contract with a Module C2 or D body, and following agreement use a valid notified body number in the place of 'XXXX' when production starts and before placement on the market, under a legally enforceable contract with that notified body.

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical 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:

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/00.053 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

instructions for use

Question:

What can notified bodies do to ensure that the information supplied by the manufacturer is legible?

Solution:

When checking the information supplied by the manufacturer, notified bodies should point out to the manufacturer that the printed version must be presented in a way that it is legible for the user.

They should make the manufacturer aware of relevant documents such as

- IEC 82079-1 “Preparation of instructions for use – structuring, content and presentation – Part 1: General principles and detailed requirements”, that specifies requirements for the presentation of instructions of use, e.g. font sizes;
- ISO IEC Guide 37:2012 “Instructions for use of products by consumers”;
- “Guideline on the readability of the labelling and package leaflet of medical products for human use” (version of 12/01/2009).

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Groups ☒ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

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

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☐ Horizontal Committee 12/06/2017 ☒ EU PPE Working Group 23/01/2018

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.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.056 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: II, 2.4 Clause:

Key words:

date of manufacture / obsolescence on the product marking

Question:

Is it necessary to include in the label / marking of each product of PPE the date of manufacture or obsolescence?

Solution:

Not in all cases.
It has to be marked if annex II, 2.4 paragraph I of the PPE Regulation applies or it is required by the relevant standard or specification.

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.058 Version 3

Number of pages: 1	Approval stage : Approved on :
Origin : French coordination	☐ Vertical Group ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Clause:

Key words:

EU type-examination certificate / re-certification / transitional period

Question:

Can the simplified procedure (Annex V, 7.6) be a basis for the conversion of EC type-examination certificates (which comply with the PPE Directive) into EU type-examination certificates (in compliance with the PPE Regulation)?

Solution:

Yes, unless:

- the manufacturer is not able to declare that no modification on the type of the product or on the technical file has occurred since the EC type-examination certificate has been issued or;
- the generally acknowledged state of the art (standard, RfUs, etc.) has changed since the EC type-examination occurred, in such a way that the product may no longer comply with the applicable essential health and safety requirements of the PPE Regulation or;
- data arising from Annex III, point 2 of the PPE Directive is not submitted by the manufacturer (notified bodies can ask for representative test data covering the life of the certificate).

In this case they have to follow the full conformity assessment procedure (Article 19 PPE Regulation).

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.061 Version 2

Number of pages: 1	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 30/05/2018 ☒ EU PPE Working Group 22/04/2019

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

Article: Annex: Annex III, b), Annex V, 2 Clause:

Key words:

Risk assessment

Question:

What is required by the manufacturer and the notified body as far as risk assessment is concerned?

Solution:

The adequate analysis and assessment of the risk(s) is the responsibility of the manufacturer.

The manufacturer describes the identified risks and shows the related sections of standards / specification plus the associated assessment method, e.g. analysis, inspection, test.

The notified body reviews the documentation to ensure that

- the risks are correctly identified with respect to the application made and the PPE presented
- the submitted user information reflects the identified risks and includes associated limitations of use as far as the requirements of the PPE Regulation are concerned.

	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.069 Version 04

Number of pages: 2	Approval stage : Approved on :
Origin: Horizontal Committee Advisory Panel	☐ Vertical Group ☒ Horizontal Committee 22/11/2023 ☒ EU PPE Expert Group 26/05/2024

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

Article: Article 34(2) Annex: V, VII, VIII Clause:

Key words:

Issues relating to negative conformity assessment results / refused / withdrawn / suspended / restricted

Question:

How does a notified body fulfil the obligation to provide information to other notified bodies conducting similar activities on issues relating to negative conformity assessment results?

Solution:

While CIRCABC provides a forum for all notified bodies to participate in discussions, by establishing 'Notified Body representative' profiles we have a dedicated sub-membership available to provide information to specific notified bodies carrying out similar conformity assessment activities (as per Article 34(2)).

Therefore, information shall be sent by the deciding notified body declaring the negative conformity assessment results to all the relevant notified bodies carrying out similar conformity assessment activities via the 'Notified Body representative' CIRCABC sub-members of the applicable VG groups.

The common approach adopted should be (the reason provided should be factual):

"Dear Notified Bodies,

Notified Body XXXX has refused / withdrawn / suspended / otherwise restricted certification / approval decisions for:

Manufacturer:

Address:

Certificate(s) / Approval Decisions Affected / Types:

Product Standard(s):

Reason:

- non-compliance in type testing (Annex V, Module B).
- non-compliance in product checks (Annex VII, Module C2).
- non-fulfilment of obligations arising out of the approved quality system (Annex VIII, Module D)
- European Union safeguard procedure - failure of the PPE to meet requirements (Article 38(5)(a)) discovered in Market Surveillance
- European Union safeguard procedure - shortcomings in harmonised standard (Article 38(5)(b)) discovered in Market Surveillance
- other reasons to be specified.

Effective from: DD Month YYYY"

ANNEX TO PPE-R/00.069
INSTRUCTIONS ON HOW TO USE CIRCABC

1. Go to the applicable Vertical Group main page;
2. Click on “Forum”;
3. Click on “Add”;
4. Click on “Topic”;
5. Write the Topic title and click on “Create”;
6. Click on “Add a new comment”.

Note: When you make a new topic, do not fill in the box called 'Description'. This will not be sent to subscribers. Make the Topic (title only) and then close the dialog. Then click on the Topic title, and put your question into a new comment. This message will be sent by email to subscribers.

	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.072 Version 02

Number of pages: 1	Approval stage: Approved on:
Origin: Horizontal Committee	☐ Vertical Group ☒ Horizontal Committee 16/05/2023 ☒ EU PPE Expert Group 31/01/2025

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

Article: Annex: Clause:

Key words:

Test method standards, dated, undated

Question:

Product standards often refer to specific standards or other sources for the specification of test methods. Changes in the test method can result in differences with regard to the interpretation of test results for the assessment of the product, e.g. with regard to performance levels. What should notified bodies do when a test method standard is dated or undated?

To claim compliance to a product standard, a manufacturer cannot deviate from its requirements.

If the product standard includes a dated reference to another standard, that specific dated-version of the standard has to be used.

Where the product standard includes an undated reference to another standard, the latest published version of the test method has to be used. The latest published version should then be checked for changes that may affect conformance with the Essential Health and Safety Requirements. A decision on the acceptance of the latest published version shall be recorded by the notified body.

NOTE 1: If a test method standard has been revised, the consequences for the interpretation of test results should be discussed in the PPE notified body coordination group and an amendment to the product standard be proposed as quickly as possible, if necessary.

NOTE 2: Use of the latest published version of a test method, due to an undated reference within a product standard, may affect the presumption of conformity if the test method assessed at time of entry into the Official Journal was an earlier version.

	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.075 Version 01

Number of pages: 1	Approval stage: Approved on:
Origin: NB 2849	☐ Vertical Group ☒ Horizontal Committee 22/11/2023 X EU PPE Expert Group 26/05/2024

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

Article: Annex: V: 6.1, 6.2(i), 7.5, 7.6 Clause:

Key words:

Renewal date, renewal, review, simplified review

Question:

How may a Notified Body represent issue and renewal dates, following review, to ensure compliance with Annex V 6.1 and 6.2(i), where the renewal process has complied with Annex V 7.5 and 7.6?

Solution:

To avoid punishing manufacturers who are early in application for renewal, and achieve early renewal, notified bodies may permit the continued use of the originating certificate where no change has occurred, for the remaining validity period.

Where a change has occurred, the notified body must consider if the originating certificate may retain validity, or must be suspended, reduced or withdrawn.

A post-dated type-examination certificate may be issued following positive renewal, inclusive of a new period of validity of up to 5 years.

The post-dated issued renewal type-examination certification should contain the following information:

- the date of first issue,
- the date of expiration of the previous period of validity, starting the new period of validity,
- the date on which the period of validity of renewal expires.

Additionally, there could be an explanation of the type of renewal, for example:

- “Reissued following simplified review procedure.”
- “Reissued following review procedure, inclusive of Amendments considering Change in the State of the Art.”
- “Reissued following review procedure, inclusive of Amendments to technical documentation.”
- “Reissued following review procedure, inclusive of Amendments to product.”

Note 1: While ISO 17065:2012, Cl 7.7.1 does require that the date certification is granted does not precede the date on which the decision is completed, it does not exclude specifying an effective granting date which succeeds the date on which the decision was completed.

Note 2: ISO 17020:2012 does not exclude specifying an effective granting date which succeeds the date on which the decision was completed.