



CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425

RECOMMENDATION FOR USE

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Origin : HCNB Advisory Panel

Approval stage :

Approved on :

Vertical Group
 Horizontal Committee
 EU PPE Expert Group

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Question related to PPE Regulation PPE

EN/prEN:

Other:

Article: Annex: V

Clause: 4(f), 7.1, 7.2, 7.4(b)

Key words:

State of the art / EU type examination

Question:

When conducting EU type-examination for a manufacturer, which standards and technical specifications available to the notified body (NB) should be considered when assessing the conformity of a product, and considering “state of the art”?

Solution:

The obligations of manufacturers and notified bodies with respect to the use of harmonised standards and other technical specifications are laid down in the PPE Regulation. Please refer to Article 3(9), Article 8(4), Article 32(3), Annex II preliminary remark 4, Annex III point (g), Annex V points 3(c), 4(d), 4(f), and 6.2(f), and Annex VII point 4.3, among others, and the clarifications provided in the PPE Regulation guidelines on this regard.

The ‘change’ must be ‘generally acknowledged’ to require notified body action on certificates issued. “Generally acknowledged” means widely available to economic operators and notified bodies, freely or through common purchase.

The table 1 below is for information purposes, and shows what common standards and or technical specification sources are available, and whether they could be considered ‘generally acknowledged’.

Table 1

Item No	Type / nature of document	Remarks – Generally Acknowledged?
1	Harmonised standard	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.
2	RFU endorsed by European Commission (horizontal and vertical RFUs)	Publicly available, via EC's PPE homepage, for free: https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment-ppe_en To be considered by NBs as per PPER Annex V, 7.1.
3	Published European standard (CEN/CENELEC)	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1
4	Horizontal RFU approved by HC (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
5	VG RFU approved by HC (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
6	Other National / International Standards	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.
7	Industry Standards / Technical Specifications	Publicly available, typically for free. To be considered by NBs as per PPER Annex V, 7.1.
8	Private developed protocol by NB for specific product	Private / Confidential to single Manufacturer. To be considered by NBs in PPER Annex V, 7.1.
9	Standard Project (TS, pr or other drafts)	Not to be considered by NBs in PPER Annex V, 7.1.