



CO-ORDINATION OF NOTIFIED BODIES  
PPE Regulation 2016/425

PPE-R/00.067  
Version 1

RECOMMENDATION FOR USE

|  |  |                                   |                                 |
|--|--|-----------------------------------|---------------------------------|
| Number of pages: 1   | Approval stage :                                   | Approved on :                     |                                 |
| Origin : French Coordination of NB   | <input type="checkbox"/> Vertical Group            | n/a                               |                                 |
|  | <input type="checkbox"/> Horizontal Committee      |                                   |                                 |
|  | <input type="checkbox"/> EU PPE Working Group      |                                   |                                 |
| Question related to  | <input checked="" type="checkbox"/> PPE Regulation | <input type="checkbox"/> EN/prEN: | <input type="checkbox"/> Other: |
| Article:   | Annex: II  | Clause: 1.4                       |                                 |
| Key words:   |  |                                   |                                 |
| Universal information for use  |  |                                   |                                 |
| Question:  |  |                                   |                                 |
| Is it possible for a manufacturer placing several different PPE types on the market to draw up a single "universal" documented instructions for use covering all PPE?  |  |                                   |                                 |
| Solution:  |  |                                   |                                 |
| Yes.   |  |                                   |                                 |
| The NB must check as part of the EU type examination.  |  |                                   |                                 |
| However, when assessing PPE, the NB must validate the documented instructions for use which is part of the technical documentation and ensure the following:   |  |                                   |                                 |
| <ul style="list-style-type: none"><li>• A PPE is assessed by only one Notified Body, the name of this body appears on the instructions to assist the market surveillance authorities. Several Notified Bodies cannot be listed on the same notice unless a clear distinction is made as to which NBs have been assessed by which of the PPE.</li><li>→ The NB need only to check that its name is clearly identified with the PPE for which it have carrying out the conformity assessment. NB will not check the accuracy of information relating to PPE for which it has not been commissioned.</li><br/><li>• The instructions for use should identify the risk for which the PPE has been designed for protection purposes and the corresponding limits of use.</li><li>→ The NB must ensure that the risks covered by the use of the PPE for which it have carrying out the conformity assessment are clearly identified in the PPE. Mention of a series of generic risks covered by the same standard but not necessarily applicable to the product does not identify its intended use, nor does it provide an understanding of the limits of use actually applicable to the product.</li><br/><li>• Documented instructions for use are needed for products. As such there must be a link, either by reproducing all product references, a family reference, or a code reproduced on the product and universal instruction.</li><li>→ The instructions must be linked to the product, and that the sections applicable to the PPE are clearly identified.</li></ul> |  |                                   |                                 |