



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.076
Version 03,
01/07/2024

RECOMMENDATION FOR USE

Number of pages: 1	Approval stage:	Approved on:
Origin: NB0161 + NB2849	<input type="checkbox"/> Vertical Group n/a <input checked="" type="checkbox"/> Horizontal Committee <input type="checkbox"/> EU PPE Expert Group	01/07/2024
Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN: <input type="checkbox"/> Other:
Article: Point 10, Article 2 Annex: II, Pre-lim 2 & 5, & 1.2.1. Clause:		
Key words: Market surveillance / foreseeable uses		
Question: If the design of PPE appears to offer protection for a foreseeable use, and the manufacturer provides only a warning against that foreseeable use within user instructions, is the manufacturer obliged to comply with EHSR obligations for this foreseeable risk? A clear example is garments with retroreflective elements that do not meet the amount of material according to product standards, but could be perceived to signal the user's presence visually.		
Solution: Yes. The manufacturer is obliged to comply with the foreseeable conditions of use, so as not to create risks. If a particular design conveys a use for which protection is not offered, then the manufacturer has not met their EHSR obligation 1.2.1 – i.e. to design so as not to create risks. It is therefore mandatory that the design of the PPE be adapted to comply with the regulations, else a positive type-examination decision cannot be given. The notified body should ensure all the appropriate adaptations are applied by the manufacturer so as not to create risks. Design adaptations shall include physical design change of the PPE to eliminate the design elements that give a perception of a non-intended foreseeable use. If physical design change is not technically possible or if the design change is insufficient to eliminate potential for misuse, the following options can be applied on the product: . - Colour coding and/or pictograms to identify specific intended uses (e.g. Respiratory Filters colour bands). - Written statements indicating for which specific use the PPE is intended . - Colour coding and/or pictograms to warn users of non-intended uses (e.g. RTFA forbidding loading over an edge pictogram). - Written warnings against specific non-intended uses.		