	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.053 Version 1

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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).