



CO-ORDINATION OF NOTIFIED BODIES  
PPE Regulation 2016/425

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Version 1

RECOMMENDATION FOR USE

Number of pages: 1		Approval stage :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	n/a
		<input checked="" type="checkbox"/> Horizontal Committee	30/05/2018
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Question related to	<input type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> 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			
<ul style="list-style-type: none"><li>• 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;</li><li>• ISO IEC Guide 37:2012 "Instructions for use of products by consumers";</li><li>• "Guideline on the readability of the labelling and package leaflet of medical products for human use" (version of 12/01/2009).</li></ul>			