

CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425

PPE-R/00.045

Version 03

RE	C	٥N	ΛM	EN	IDA	TIO	N	FOR	USE
----	---	----	----	----	-----	------------	---	------------	-----

Number of pages: 1			Approval stage :	Approved on :						
Origin : Horizontal C	ommittee		□ Vertical Group☑ Horizontal Committee☑ EU PPE Expert Group	16/05/2023 31/01/2024						
Question related to		es EN/prE	N:	☐ Other:						
Article: : 3 (1) (b)	Annex:	Clause:								
Key words: Article 3(1)(b); interchangeable components for equipment referred to in point (a) which are essential for its protective function										
Question:										
Who can apply for EU type-examination of interchangeable components in the meaning of Article 3, (1) (b) of the PPE Regulation?										
Solution:										
The situation will depend on the PPE presented. Some performance standards have design restrictions that present a common/standardised approach (e.g. EN 148-1 "Respiratory protective devices - Threads for facepieces - Part 1: Standard thread connection) - such that the PPE continues to perform provided each Manufacturer produces in conformity with the standard. So therefore, any applicant may apply.										
Where no such standard exists, the Notified Body must assess the risk of a change by one manufacturer, on the potential conformity of the second manufacturer proposing an interchangeable part. In this case the manufacturer of the interchangeable component must ensure it is identical to the manufacturer's original components in safety performance, and there must be a contractual agreement between them, which authorises the manufacturer of the interchangeable component.										
(see also RfU 00.027, 00.035, 00.046)										