

CO-ORDINATION OF NOTIFIED BODIES

PPE-R/03.039

* *	PPE	Regulation 2016/425	Version 01
*	RECO	MMENDATION FOR USE	
Number of pages: 1		Approval stage :	Approved on :
Origin : NB2849		✓ Vertical Group✓ Horizontal Committee✓ EU PPE Expert Group	11/02/2025 20/03/2025
Question related to] PPE Regulation	☑ EN/prEN: EN ISO 16321-1:2022	Other:
Article:	Annex:	Clause: 4.4	
Key words: cleaning and	disinfection – quantity to be eva	uated	
Question:			
The number of test specir	nens to be evaluated in relation	to cleaning and disinfection requirement is unclear.	
Clause 4.4: "The protecto be supplied by the manufa	rs shall be cleaned only once in acturer before being subjected t	accordance with the cleaning and/or disinfection proof testing."	cedures in the information to
Table 20, page 30 and Ta	ble 21, page 33 - Number of tes	st specimens to be evaluated: "1"	
What is the quantity to be	evaluated?		
Solution:			
All specimens should be o	cleaned prior to proceeding to fu	orther testing.	