

## **CO-ORDINATION OF NOTIFIED BODIES** PPE Regulation 2016/425

PPE-R/05.26-00 <sup>2</sup>
Version 02

^	RECOMMENDATION FOR USE			
Number of pages: 1		Approval stage:	Approved on:	
Origin: Vertical Grou	p 5	<ul><li>✓ Vertical Group</li><li>✓ Horizontal Committee</li><li>✓ EU PPE Expert Group</li></ul>	16.06.2021 01.10.2021 18.11.2022	
Question related to			Other:	
Article:	Annex:	Clause:		
Key words: Breathable spray-tig	ht			
Question:				
The BSIF PSMA committee have identified a need for, and advantages of, development of a standard suitable for "breathable" spray-tight protective garments; they have highlighted a number of issues with the current permeation test called up for Type 4 garments (through EN 14605 which references EN 14325 Clause 4.11). Work to address the issues is ongoing at CEN level. In the meantime, there are applications which require a higher level of liquid spray protection than that offered by a Type 6 garment; but do not necessarily need the chemical permeation resistance specified in EN 14605 for a Type 4 garment (Examples of which include applications requiring decontamination by a shower following hazardous particulate contamination). Whilst the standards are being reviewed to address this issue, how should Notified Bodies CE certify these kinds of products?				
Solution:				
For Type 6 products, including those which are breathable*, which are to be marketed as "spray-tight":				

- Product shall meet all requirements of EN 13034;
- Product shall additionally be tested in accordance with ISO 17491-4 (Method B, High Level Spray Test);
- Product shall pass the spray test as per the requirement of EN 14605 4.3.4.2;
- The spray-tight shield may be used on product packaging and user information;
- The user instructions and CE certificate shall clearly indicate that the product meets the spray-test requirements of EN 14605 only and does not claim the Type 4 standard.
- The User Instructions shall relate the recommended decontamination process to the spray test performance.
- \* The generally accepted definition of "breathable" materials is those that are moisture and/or air permeable. PD CEN TR/ 15419:2006 define air-permeable materials as "materials with pores or apertures that allow the transmission of gases". In order to demonstrate that a material is breathable a manufacturer shall test to EN 31092 (test method for water vapour resistance) as specified in EN13688:2013 4.4.2 and shall achieve Class 2 or 3 (according to EN 343).

NOTE: If and when the standards are revised to provide for this particular kind of product; this guidance sheet should be reviewed.