

EU Declaration of Conformity

Manufacturer:	Polyco Healthline Ltd.
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Polyco
Product Description:	Processor II
Product Code:	72
PPE Category:	Category III

It is declared that the above product:


is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 388:2016+A1:2018, EN 420:2003+A1:2009 and EN 421:2010.

Standard	Performance Levels	
EN 388:2016+A1:2018	1010X	
EN ISO 374-1:2016+A1:2018	Type A - KLMPST	
EN ISO 374-5:2016	Protection Against Bacteria & Fungi	Protection Against Viruses
	Pass	n/a
EN 421:2010	Particulate radioactive contamination only.	

is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/10430-03/E02-01, issued by SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.

is subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS Fimko Oy, P. O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland (Notified Body number 0598).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Polyco Healthline Ltd.

Signed for and on behalf of: Polyco Healthline Ltd
Place and date of issue: Bourne, 18th July 2023
Name and role: David Langridge, Laboratory and Technical Manager
Signature: 
Expiry Date: 01st December 2023