

EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER

Name of Company	Address
Polyco Healthline Ltd	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.

EU IMPORTER

Name of Company	Address
Polyco Healthline BV	7 th Floor, De Boelelaan 7, Amsterdam, 1083HJ

PRODUCT IDENTIFICATION

Product Name	Code / Catalogue Number
Shield Blue Polysynthetic Powder Free	GD75
Intended Purpose	Photograph
Food Manufacturing and Preparation; Medical, Vet and Dental.	

RISK CATEGORY OF PERSONAL PROTECTIVE EQUIPMENT AND PERFORMANCE LEVELS

Product Risk Category		
Personal Protective Equipment (PPE) Category III		
Standard	Performance Levels	
EN ISO 374-1:2016	Type C - K	
EN ISO 374-5:2016	Protection against bacteria and fungi	Protection against viruses
	Pass	Not assessed

Polyco Healthline Ltd declares that the above-mentioned product meets the provisions of the following EU legislation:

- is classed as Category III PPE 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, EN ISO 374-5:2016 and EN 420:2003 + A1:2009.
- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11324-02/E00-00, 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.

Head Office & Distribution Centres: South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK

www.polycohealthline.com Tel: +44 (0)33 3320 8550

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- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777).

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

DATE: 20th February 2024