

EU Declaration of Conformity

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

MANUFACTURER

Name of Company	Address	SRN
Polyco Healthline Ltd	South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK	GB-MF-000015289

AUTHORIZED REPRESENTATIVE

Name of Company	Address	SRN	Phone/email
International Associates Auditing & Certification Limited	The Black Church, St Mary's Place, Dublin 7, D07 P4AX Ireland	IE-AR-000002248	+353 16971561 EUAR@ie.ia-net.com

PRODUCT IDENTIFICATION

Product Name	Code / Catalogue Number	Basic UDI-DI
Vinyl Powder Free Disposable Glove	GN65	5024951GVPFNS004M
Intended Purpose	Photo	
Examination gloves for non-invasive use to prevent contact with skin, bodily fluids, and chemicals. Invasive with respect to natural body orifices.		

RISK CLASS FOR MEDICAL DEVICES

Device Classification		Common Specifications / Standards	
Class:	I	EN455-1:2020	Medical gloves for single use: Freedom from holes
Rule:	5	EN455-2:2015 EN455-3:2015 EN455-4:2009	Medical gloves for single use: Physical properties Medical gloves for single use: Biological evaluation Medical gloves for single use: Shelf-life determination

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 + A1:2018		Type C - K
EN ISO 374-5:2016		Protection against bacteria and fungi
Pass		Protection against viruses
Pass		Pass

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

- Medical Devices Regulation (EU) 2017/745
- Is classed as Cat III PPE in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonized standards EN ISO 374-1:2016+ A1:2018, 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 2777/11947-03/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.
- 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

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