

## 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 ODN. 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 <a href="mailto:EUAAR@ie.ia-net.com">EUAAR@ie.ia-net.com</a>

### EU IMPORTER

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

### PRODUCT IDENTIFICATION

Product Name	Code / Catalogue Number	Basic UDI-DI
Blue Nitrile Powder Free Examination Glove	GN83	5024951GNPFNS00YA
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
		EN455-2:2015	Medical gloves for single use: Physical properties
Rule:	5	EN455-3:2015	Medical gloves for single use: Biological evaluation
		EN455-4:2009	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	Protection against viruses
	Pass	Pass

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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 harmonised standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, and EN ISO 21420:2020.
- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11245-02/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.
- 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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