


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

PRODUCT IDENTIFICATION		
Product Name	Code / Catalogue Number	Basic UDI-DI
Blue Nitrile Powder Free Examination Glove	SD91E	5024951GNPFNS00YA
Intended Purpose	Photograph	
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	Medical gloves for single use: Freedom from holes
	EN455-2	Medical gloves for single use: Physical properties
Rule: 5	EN455-3	Medical gloves for single use: Biological evaluation
	EN455-4	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 B - KPT	
EN ISO 374-5:2016	Protection against bacteria and fungi	Protection against viruses
	Pass	Pass

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Page 2 of 2



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 2777/11509-10/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 D2 set out in Annex VIII 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

**PLACE:** Bourne, UK

**SIGNATURE:** *David Langridge*

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