Polyco Healthline
Tel: +44 (0)33 3320 8550

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

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

PRODUCT IDENTIFICATION		
Product Name	**Code / Catalogue Number**	**Basic UDI-DI**
Purple Nitrile Powder Free Examination Glove	MFNP100	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 EN455-3:2015 Medical gloves for single use: Biological evaluation EN455-4:2009 Medical gloves for single use: Shelf-life determination
Rule:	5	

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 420:2003+A1:2009.
- Is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11392-03/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:** D Langridge

PLACE: Bourne, UK **ISSUE DATE:** 16th February 2024