


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
Pink Nitrile Powder Free Examination Glove	GN560	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	Medical gloves for single use: Freedom from holes
Rule:	5	EN455-2	Medical gloves for single use: Physical properties
		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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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 2777/21054-02/E19-01, 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

PLACE: Bourne, UK

SIGNATURE: 

ISSUE DATE: 16th June 2025