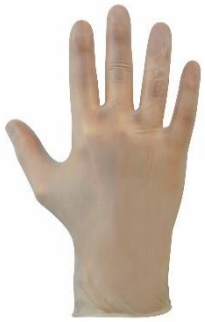
Polyco Healthline
Tel: +44 (0)33 3320 8550

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

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	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 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 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:**	D Langridge
PLACE:	Bourne, UK	**ISSUE DATE:**	17th June 2025