


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 Examination Glove	GN67	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	EN455-1:2020	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

Polyco Healthline Ltd declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- Is classed as Cat I PPE Minimal Risk in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment.

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

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