


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
Stretch Synthetic Polymer Powder Free Examination Glove	FT130	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
	EN455-3:2015	Medical gloves for single use: Biological evaluation
Rule: 5	EN455-4:2009	Medical gloves for single use: Shelf-life determination

Polyco Healthline Ltd declares that the above-mentioned product meets the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

ISSUE DATE: 05th February 2024

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