


EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER			
Name of Company	Registered Office	Trading Address	SRN
Medicare Products Ltd	South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK	Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ, UK	GB-MF-000011612

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 / Catalog Number	Basic UDI-DI
Blue Nitrile Powder Free Examination Glove (Nitrex Extra Sensitive)	GN01	506004079GNPFNS00LX
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
Rule: 5	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

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 – K, T, P	
EN ISO 374-5:2016	Protection against bacteria and fungi	Protection against viruses
	Pass	Pass
EN388:2016 + A1:2018	N/A	
EN407:2020	N/A	
EN511:2006	N/A	

Medicare Products 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 374-1:2016+A1:2018, EN 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 2777/10015-07/E01-01, 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

SIGNATURE: 

PLACE: Bourne, UK

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