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**
Nitrile Powder Free Examination Glove (Nitrex)	GN05	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
		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

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, T	
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 420:2003+A1:2009.
- Is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/12062-03/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 quality assurance conformity of the production process Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS FIMKO OY, Särkiniementie 3, 00211 Helsinki, Finland (Notified Body Number 0598).

COMPANY REPRESENTATIVE:	David Langridge		
TITLE:	Head of Technical	**SIGNATURE:**	D Langridge
PLACE:	Bourne, UK	**ISSUE DATE:**	06 March 2024
EXPIRY DATE:	06 March 2029		