


## 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 <a href="mailto:EUAR@ie.ia-net.com">EUAR@ie.ia-net.com</a>

PRODUCT IDENTIFICATION		
Product Name	Code / Catalog Number	Basic UDI-DI
Nitrile Powder Free Sterile Cleanroom Gloves (NITREX 600)	GN38	N/A
Intended Purpose	Photo	
Cat III PPE for use in cleanrooms and offering a degree of chemical protection against the chemicals specified in the IFU.		

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standards
Class:	N/A	N/A
Rule:	N/A	

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	Type C	
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	

Document Reference: ME-EUDOC-034  
Document Issue Number: 03  
Document Issue Date: 18/03/2026  
Document Review Date: 18/03/2026  
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Medicare Products Ltd declares that the above-mentioned product meets the provision of the following EU legislation:

- 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, 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 2777/11793-03/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:** *David Langridge*

**PLACE:** Bourne, UK

**ISSUE DATE:** 18 March 2026

**EXPIRY DATE:** 18 March 2031