

EU Declaration of Conformity

Manufacturer:	Medicare Products Ltd
Manufacturer's Address:	Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ
Product Brand:	Nitrex Ultra Sensitive
Product Description:	Blue nitrile powder free disposable glove
Product Code:	GN92
PPE Category:	Category III
Medical Device Category:	Class I

It is declared that the above product:

- is 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 2777/10015-03/E13-01, 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).
- is in conformity with the provisions of regulation (EU) 2017/745 of the European parliament on medical devices and national standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, and is self-certified as a Class 1 non-sterile medical device (according to Annex VIII rule 5).

Unique Device Identification (UDI-DI)-GTIN

Sizes	Inner Dispenser Barcode	Outer Case Barcode
X-Small	5060040790243	5060040790267
Small	5060040798737	5060040798706
Medium	5060040798744	5060040798713
Large	5060040798751	5060040798720
X-Large	5060040790236	5060040790250

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Medicare Products Ltd.

Signed for
and on behalf of: Medicare Products Ltd

Place of issue: Bourne

Name and role: Karen Gunning,
QARA Manager

Signature:



Expiry Date: 21st April 2023