

EU Declaration of Conformity

Manufacturer:	Medicare Products Ltd.
Manufacturer's Address:	Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ UK.
Product Brand:	Nitrex CX400
Product Description:	Nitrile, powder free disposable glove, 400mm Length. Non-Sterile. Available in blue and white.
Product Code:	GN34
PPE Category:	Category III
Medical Device Category:	Class I
Conformity Route:	Annex VII self-declaration

It is declared that the above product:

PPE:

is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, and EN 420:2003+A1:2009.

Standard	Result
EN ISO 374-5:2016	Protection against Bacteria and Fungi - Pass Protection against Viruses - Pass


is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11793-01/E04-01, issued by SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Ireland (Notified Body No. 2777), according to Annex V (Module B) of Regulation (EU) 2016/425.

is subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS United Kingdom Ltd, Unit 202B, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom. (Notified Body: 0120).

Medical:

is in conformity with the provisions of Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, 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 IX rule 5).

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 and date of issue: Purfleet, 26th June 2019
Name and role: Gary Sira, Director
Signature: 
Expiry Date: 28th January 2024