

EU Declaration of Conformity

Manufacturer:	Medicare Products Ltd.
Manufacturer's Address:	Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ UK.
Product Brand:	Nitrex Extra Sensitive
Product Description:	Nitrile powder free disposable glove. Non-Sterile. Available in blue and white.
Product Code:	GN01
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	Scores
EN ISO 374-5:2016	Pass / Pass

is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 0321/10015-02/E01-01, issued by SATRA Technology Centre Ltd, Wyndham Way, Kettering NN16 85D United Kingdom (Notified Body number 0321), 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 Centre Ltd, Wyndham Way, Kettering NN16 85D United Kingdom (Notified Body number 0321).


Medical:

is in conformity with the provisions of Council Directive 93/42/EEC 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).

Food contact:

is in conformity with regulation (EU) 1935/2004 and has been tested in accordance with EN 1186 and is suitable for use with all categories of foodstuffs for short periods of repeated contact.

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, 3rd May 201
Name and role: Gary Sira, Director
Signature: 
Expiry Date: 21st April 2023