

EU Declaration of Conformity

Manufacturer:	Polyco Healthline Ltd.
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	SafeDon
Product Description:	Nitrile powder free blue disposable glove refill
Product Code:	GX994
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 2777/11580-01/E00-00, 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 Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK (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).

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Page 2 of 2

Food contact:

is in conformity with regulation (EU) 1935/2004 and has been tested in accordance with EN1186 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, Polyco Healthline Ltd.

Signed for and on behalf of: Polyco Healthline Ltd
Place and date of issue: Bourne, 13th June 2019
Name and role: David Langridge, Laboratory and Technical Manager
Signature: 
Expiry Date: 22nd November 2023