Polyco Healthline
Tel: +44 (0)33 3320 8550

EU Declaration of Conformity

Manufacturer:	Polyco Healthline Ltd
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	HandSafe
Product Description:	Indigo nitrile powder free disposable glove with long cuff
Product Code:	GN830
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 2777/11245-01/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 Europe Limited, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Republic of Ireland (Notified Body number 2777).

- 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).

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 of issue:	Bourne
Name and role:	Karen Gunning, QARA Manager
Signature:	
Expiry Date:	21st September 2023