

EU Declaration of Conformity

Manufacturer:	Polyco Healthline Ltd
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Newton / HandSafe
Product Description:	Nitrile powder free disposable glove
Product Code:	GN90
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 ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN 420:2003+A1:2009.

Standard	Performance Levels	
EN ISO 374-1:2016+A1:2018	Type C - K	
EN ISO 374-5:2016	Protection Against Bacteria & Fungi	Protection Against Viruses
	Pass	Pass

- is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11580-06/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 Regulation (EU) 2017/745 on medical devices and with National Standards transposing harmonised standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009, and is self-certified as a Class 1 non-sterile medical device (according to Annex VIII 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 and date of issue: Bourne, 24th May 2021
Name and role: David Langridge, Head of Technical
Signature: 
Expiry Date: 22nd November 2023