INTEGRITY™
CLEANROOM PRODUCTION SOLUTIONS

UKCA Declaration of Conformity

Manufacturer:	Polyco Healthline Ltd
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Bodyguards
Product Description:	Finite P Indigo AF (purple nitrile powder free examination glove)
Product Code:	MFNP100
PPE Category:	Category III
Medical Device Category:	Class I
Medical Device Basic UDI-DI:	5024951GNPFNS00YA

It is declared that the above product:

- is in conformity with the provisions of Regulation (EU) 2016/425 as brought into UK law and amended on personal protective equipment and with designated standards EN ISO 374-1:2016, EN ISO 374-5:2016 and EN 420:2003+A1:2009.

Standard	Performance Levels	
EN ISO 374-1:2016	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 UKCA Type-Examination Certificate number 0321/17141-01/E00-00, issued by SATRA Technology Centre Limited, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom (Approved Body number 0321), according to Annex V (Module B) of Regulation (EU) 2016/425 as brought into UK law and amended.

- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425 as brought into UK law and amended, under the surveillance of the approved body SATRA Technology Centre Limited, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom (Approved Body number 0321),

- is in conformity with the provisions of UK MDR 2002 (SI 2002 No. 618, as amended) on medical devices and with designated standards EN 455-1:2020, 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 IX rule 5).

This UKCA 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, 6th August 2021
Name and role:	David Langridge, Head of Technical
Signature:	D Langridge
Expiry Date:	24th June 2026