

## UKCA Declaration of Conformity

|                                     |   |
|-------------------------------------|---|
| <b>Manufacturer:</b>                | Polyco Healthline Ltd                               |
| <b>Manufacturer's Address:</b>      | South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK. |
| <b>Product Brand:</b>               | HandSafe  |
| <b>Product Description:</b>         | Blue nitrile powder free examination glove          |
| <b>Product Code:</b>                | GN91  |
| <b>PPE Category:</b>                | Category III  |
| <b>Medical Device Category:</b>     | Class I   |
| <b>Medical Device Basic UDI-DI:</b> | 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 0321/17145-01/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, 9<sup>th</sup> August 2021  
Name and role: David Langridge, Head of Technical  
Signature:   
Expiry Date: 24<sup>th</sup> June 2026