


EU Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

| MANUFACTURER | | |
|-----------------------|--|-----------------|
| Name of Company | Address | SRN |
| Polyco Healthline Ltd | South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK | GB-MF-000015289 |

| Name of Company | Address | SRN | Phone/email |
|---|---|-----------------|---|
| International Associates Auditing & Certification Limited | The Black Church, St Mary's Place, Dublin 7, D07 P4AX Ireland | IE-AR-000002248 | +353 16971561 EUAR@ie.ia-net.com |

| EU IMPORTER | |
|----------------------|--|
| Name of Company | Address |
| Polyco Healthline BV | 7 th Floor, De Boelelaan 7, Amsterdam, 1083HJ |

| PRODUCT IDENTIFICATION | | |
|---|--|-------------------|
| Product Name | Code / Catalogue Number | Basic UDI-DI |
| Blue Nitrile Powder Free Examination Glove | GN90 | 5024951GNPFNS00YA |
| Intended Purpose | Photo | |
| Examination gloves for non-invasive use to prevent contact with skin, bodily fluids, and chemicals. Invasive with respect to natural body orifices. |  | |

| RISK CLASS FOR MEDICAL DEVICES | | |
|--------------------------------|---|---|
| Device Classification | | Common Specifications / Standards |
| Class: | I | EN455-1:2020 Medical gloves for single use: Freedom from holes EN455-2:2015 Medical gloves for single use: Physical properties |
| Rule: | 5 | EN455-3:2015 Medical gloves for single use: Biological evaluation EN455-4:2009 Medical gloves for single use: Shelf-life determination |

| RISK CATEGORY OF PERSONAL PROTECTIVE EQUIPMENT AND PERFORMANCE LEVELS | | |
|---|---------------------------------------|----------------------------|
| Product Risk Category | | |
| Personal Protective Equipment (PPE) Category III | | |
| Standard | Performance Levels | |
| EN ISO 374-1:2016 | Type C - K | |
| EN ISO 374-5:2016 | Protection against bacteria and fungi | Protection against viruses |
| | Pass | Pass |

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Registered in England No. 2000388 VAT Reg. No. GB 245 2922 09

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Polyco Healthline Ltd declares that the above-mentioned product meets the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- Is classed as Cat III PPE 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, EN ISO 374-5:2016, and EN ISO 21420:2020.
- Is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 2777/11580-07/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).

COMPANY REPRESENTATIVE: David Langridge

TITLE: Head of Technical

SIGNATURE: 

PLACE: Bourne, UK

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