# EU Declaration of Conformity

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

| MANUFACTURER | | | |
|---|---|---|---|
| **Name of Company** | **Registered Office** | **Trading Address** | **SRN** |
| Medicare Products Ltd | South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK | Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ, UK | GB-MF-000011612 |

| AUTHORIZED REPRESENTATIVE | | | |
|---|---|---|---|
| **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<br>EUAR@ie.ia-net.com |

| PRODUCT IDENTIFICATION | | |
|---|---|---|
| **Product Name** | **Code / Catalog Number** | **Basic UDI-DI** |
| Blue Nitrile Powder Free Examination Glove (Nitrex Extra Sensitive) | GN01 | 506004079GNPFNS00LX |
| **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 |
| **Rule:** | 5 | EN455-2:2015 | Medical gloves for single use: Physical properties |
| | | EN455-3:2015 | Medical gloves for single use: Biological evaluation |
| | | EN455-4:2009 | Medical gloves for single use: Shelf-life determination |

Medicare Products 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 374-1:2016+A1:2018, EN 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 2777/10015-07/E01-01, 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:** | D Langridge |
| **PLACE:** | Bourne, UK | **DATE:** | 04/03/2022 |

# UKCA Declaration of Conformity

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

| MANUFACTURER | | |
|---|---|---|
| **Name of Company** | **Registered Office** | **Trading Address** |
| Medicare Products Ltd | South Fen Road, Bourne, Lincolnshire, PE10 0DN. UK | Unit B, Dolphin Way, Purfleet, Essex, RM19 1NZ. UK |

| PRODUCT IDENTIFICATION | | |
|---|---|---|
| **Product Name** | **Code / Catalog Number** | **Basic UDI-DI** |
| Blue Nitrile Powder Free Examination Glove (Nitrex Extra Sensitive) | GN01 | 506004079GNPFNS00LX |
| **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 |

Medicare Products Ltd declares that the above-mentioned product meets the provision of the following UK legislation:

- Medical Devices Regulation UK MDR 2002 (SI 2002 No 618, as amended)
- Is classed as Cat III PPE in conformity with the provisions of Regulation (EU) 2016/425 as bought into UK law and amended on personal protective equipment and with designated standards EN 374-1:2016, EN 374-5:2016, and EN ISO 20420:2020
- Is identical to the personal protective equipment which is the subject of UKCA Type-Examination Certificate number AB0321/16919-01/E01-01, issued by UK Approved body 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 bought into UK law and amended.

- Is subject to the quality assurance conformity of the production process Module C2 set out in Annex VIII of Regulation (EU) 2016/425 as bought into UK law and amended, under the surveillance of the UK Approved body SATRA Technology Centre Limited, Wyndham Way, Telford Way, Kettering. Northamptonshire. NN16 8SD. United Kingdom. (Approved Body number 0321)

| | | | |
|---|---|---|---|
| **COMPANY REPRESENTATIVE:** | David Langridge | | |
| **TITLE:** | Head of Technical | **SIGNATURE:** |  |
| **PLACE:** | Bourne, UK | **DATE:** | 04 March 2022 |