MERCATOR

# EU DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLAND

SRN: PL-MF-000018942

Declares under its sole responsibility that non-sterile examination and protective gloves:

| Brand | Type | Sizes | Reference Numbers |
|---|---|---|---|
| **nitrylex® classic** | nitrile, powder-free, blue, for single use | XS (5-6) - XL (9-10) | a'100: RD30019001-05<br>a'200: RD30096001-05 |
| | nitrile, powder-free, white, for single use | XS (5-6) - XL (9-10) | a'50: RD30174001-05<br>a'100: RD30143001-05<br>a'200: RD30097001-05 |
| | nitrile, powder-free, violet, for single use | XS (5-6) - XL (9-10) | a'100: RD30169001-05<br>a'200: RD30168001-05 |
| **Basic UDI-DI:** 5906615 RD NS N PF 9C | | | |
| **Intended use:** gloves intended for use in the medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure. | | | |

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards: EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

The products described above are Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards:
EN ISO 21420:2020 / EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 / EN ISO 374-1:2016, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 / EN 374-4:2013, EN ISO 374-5:2016.

The products described above are subject to the EU Type Examination (Module B) under certificate No. 2777/10015-07/E14-01 issued by notified body:

**Satra Technology Europe Limited (2777)**
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

**Satra Technology Europe Limited (2777)**
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:
26.04.2023, Kraków

Signed on the behalf of the Manufacturer:

Leszek Garbacz
Regulatory & Documentation Manager

MERCATORMEDICAL

# EU IZJAVA O SKLADNOSTI

Proizvajalec: **MERCATOR MEDICAL S.A.**
UL. H. MODRZEJEWSKIEJ 30
31-327 KRAKOW, POLSKA

SRN: PL-MF-000018942

Izjavlja na izključno svojo odgovornost, da so ne sterilne medicinske in zaščitne rokavice:

| Znamka | Tip | Velikosti | Kataloške številke |
|---|---|---|---|
| **nitrylex® classic** | nitrilne rokavice, modre, brez pudra, za enkratno uporabo | XS (5-6) - XL (9-10) | a'100: RD30019001-05<br>a'200: RD30096001-05 |
| | nitrilne rokavice, bele, brez pudra, za enkratno uporabo | XS (5-6) - XL (9-10) | a'50: RD30174001-05<br>a'100: RD30143001-05<br>a'200: RD30097001-05 |
| | nitrilne rokavice, vijolične, brez pudra, za enkratno uporabo | XS (5-6) - XL (9-10) | a'100: RD30169001-05<br>a'200: RD30168001-05 |
| **Basic UDI-DI: 5906615 RD NS N PF 9C** | | | |
| Namen uporabe: rokavice so namenjene za uporabo na medicinskem področju za zaščito pacienta in uporabnika ter namenjene za uporabo na enem posamezniku med posameznim postopkom. | | | |

v skladu z določbami Uredbe o medicinskim pripomočkih (EU) 2017/745 Evropskega parlamenta in Sveta z dne 5. aprila 2017 o medicinskih pripomočkih, so razvrščeni kot medicinski pripomoček razreda I v skladu s prilogo VIII Uredbe (EU) 2017/745 in ustrezajo harmoniziranim standardom: EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

Izdelki so prav tako klasificirani kot osebna varovalna oprema, razvrščeni v kategorijo III in so v skladu z določbami Uredbe (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi in razveljavitvi Direktive Sveta 89/686/EGS ter ustrezajo harmoniziranim standardom: EN ISO 21420:2020 / EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018 / EN ISO 374-1:2016, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 / EN 374-4:2013, EN ISO 374-5:2016.

Izdelki ustrezajo osebni varovalni opremi, ki so predmet ugotavljanja skladnosti po EU – pregleda tipa (modul B) z izdanim certifikatom št. 2777/10015-07/E14-01 s strani priglašenega organa:

**Satra Technology Europe Limited (2777)**

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Izdelki so skladni s tipom, ki temelji na notranji kontroli proizvodnje plus nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih (modul C2) pod nadzorom priglašenega organa:
**Satra Technology Europe Limited (2777)**
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Datum in kraj izdaje:
26.04.2023, Krakow

Podpisano v imenu proizvajalca:
Leszek Garbacz
Vodja dokumentacije izdelkov