

EU DECLARATION OF CONFORMITY

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

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

| Brand | Type | Sizes | Batch numbers |
|--|--|----------------------|--|
| nitrilex® basic | nitrile, powder-free, dark blue, for single use | XS (5-6) - XL (9-10) | a'100 RD30105001-05 a'200 RD30084001-05 |
| | nitrile, powder-free, violet, for single use | XS (5-6) - XL (9-10) | a'100 RD30106001-05 a'200 RD30098001-05 |
| Basic UDI-DI: 5906615 RD NS N PF 9C | | | |

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 according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category I 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 420:2003 + A1:2009.

Date and place of issue:
 05.05.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka
 Product Documentation Manager

MERCATOR MEDICAL S.A.
 ul. Heleny Modrzejewskiej 30, 31-327 Kraków
 tel. 12 66 55 400, fax 12 66 55 415
 Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieścia w Krakowie,
 XI Wydział Gospodarczy KRS, KRS: 0000036244
 Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
 NIP: 677-10-36-424, REGON: 350967107
 Numer BDO: 000056063