MERCATOR

EU DECLARATION OF CONFORMITY

Manufacturer: **Mercator Medical (Thailand) Ltd.**
88/8 Moo.12 Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180 Thailand

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

Brand	Type	Sizes	Reference Numbers
nitrylex® classic	nitrile, powder free, for single use	XS (5-6) – XL (9-10)	RD30019901-05_0001

Basic UDI-DI: 88591852 NS N PF 6S

Intended use: non-sterile powder free nitrile examination and protective gloves for single use, intended for medical purpose that in worn on the hand to protect patient and examiners from cross contamination, conducting medical examinations, diagnostic and therapeutic procedures.

Conformity Assessment Route: Annex II and III (as per Regulation (EU) 2017/745)

classified as medical device class I, Rule 5 according to Annex VIII of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices meet the general safety and performance requirements set out in Annex I Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices and comply with standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021 and EN ISO 20417:2021. The obligations laid down in Annex IV.

The products described above are in conformity with the provision of the Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment as a Category III product, with standards EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018 and EN ISO 21420:2020.

The products are subject of EU Type Examination (Module B) under certificate No. 2777/12470-05/E00-00 and of the conformity to type 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 (Notified Body number 2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

EU Authorized Representative
Mercator Medical S.A.
ul. H. Modrzejewskiej 30 31-327 Krakow, Poland

This declaration is supported by the Quality System approval to ISO13485:2016/EN ISO13485:2016 and ISO 9001:2015 issued by:
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK

Date and place of issue:
24.08.2023, Thailand

Signed on the behalf of the Manufacturer:

Mr. Praneet Inthajak
Senior QA/RA Manager
Mercator Medical (Thailand) Ltd.

Mercator Medical (Thailand) LTD.
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