

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, blue, for single use	XS (5-6) – XL (9-10)	RD30019001-05(0001)
Basic UDI-DI: 88591852 NS N PF 6S			

classified as medical device class I according to Annex VIII of the MDR 2017/745/EU (Medical Device Regulation) meet the general safety and performance requirements set out in Annex I MDR 2017/745/EU (Medical Device Regulation) and comply with standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. The obligations laid down in Annex IV.

The products described above are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B where such is the case, with standards EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, EN 388:2016 and EN ISO 21420:2020.

The products are identical to Personal Protective equipment, which is the subject to the EU Type Examination (Module B) and Module C2 On-going Conformity under certificate No. 2777/12470-04/E00-00 issued by notified body:

SATRA Technology Europe Limited (Notified Body number 2777)

Bracetown Business Park Clonee Dublin 15 D15 YN2P, Republic of Ireland

We explicitly designate **Mercator Medical S.A.** to act as our sole Authorized Representative in the European Union for the above indicated products:

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:

30.03.2021, Thailand

Signed on the behalf of the Manufacturer:


Mr. Praneet Intajak
Senior QA/RA Manager
Mercator Medical (Thailand) LTD.


Mercator Medical (Thailand) LTD.

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