MERCATOR

DECLARATION OF CONFORMITY

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

Product: Non-sterile Powder Free Nitrile Examination and Protective Gloves

Brand	Type	Sizes	Reference Numbers
nitrylex® classic	Nitrile, powder free, blue, for single use	S (6-7) – XL (9-10)	RD30019902-05

Intended Purpose: Non-sterile powder free nitrile examination gloves intended for medical purposes that in worn on the hand to protect patient and examiners from cross contamination. Examination glove is intended for medical activities except surgery

Device Classification: Class I under Rule 5 according to Annex VIII of Regulation (EU) 2017/745

Basic UDI-DI: 88591852 NS N PF 6S

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

Declare and ensure with sole responsibility, that the abovementioned products meet the provision of the MDR 2017/745/EU (Medical Device Regulation) and comply with European standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, 455-4:2009, EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. The obligations laid down in Annex IV of the MDR 2017/745/EU (Medical Device Regulation).

The products described above are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B and PPE Regulation (EU) 2016/425 as brought into UK law and amended 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 and EN ISO 21420:2020.

The products are subject of EU Type Examination (Module B) and Module C2 On-going Conformity under certificate No. 2777/12470-05/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

The products are subject of UKCA Type Examination (Module B) and Module C2 On-going Conformity under certificate No. AB0321/17235-01/E00-00 issued by approved body:
SATRA Technology Centre Limited (Approved Body number 0321)
Wyndham Way, Telford Way, Kettering. Northamptonshire. NN16 8SD. United Kingdom

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:
04.05.2022, Thailand

Signed on the behalf of the Manufacturer:

บริษัท เมอร์กาโต้ เมดิคัล (ไทยแลนด์) จำกัด
MERCATOR MEDICAL (THAILAND) LTD.

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

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