

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® one by one	nitrile, powder free, for single use	XS (5-6) - XL (9-10)	a'200: RD30124001-05
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