MERCATOR MEDICAL

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	Reference Numbers
nitrylex® beFree long	nitrile, powder free, for single use	XS (5-6) - XL (9-10)	a'100: RD30229001-05
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 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 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

The products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/10013-03/E09-01 issued by notified body:

SATRA Technology Europe Ltd (2777)
Bracetown Business Park, Clonee, Dublin 15, Ireland

and are subject to the conformity assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body:

SGS FIMKO OY (0598)
P.O. Box 30 (Särkiniementie 3) 00211 Helsinki, Finland.

Date and place of issue:
05.05.2020, Kraków

Signed on the behalf of the Manufacturer:

Wojciech Hercka
Product Documentation Manager