MERCATOR

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
ambulance® high risk	latex, powder free, for single use	S (6-7) - XXL (10-11)	a'50: RD10011002-06
Basic UDI-DI: 5906615 RD NS L PF 92			
Intended use: non-sterile examination and protective gloves, for single use			

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, 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 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 subject to the EU Type Examination (Module B) under certificate No. CE 698940 issued by notified body:

BSI Group The Netherlands B.V. (2797)
Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands

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

BSI Group The Netherlands B.V. (2797)
Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands

Date and place of issue:
04.02.2022, Kraków

Signed on the behalf of the Manufacturer:

Leszek Garbacz
Product Documentation Manager

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