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	Basic UDI-DI
santex® anatomic	latex, powder-free, anatomic shape, for single use	6.0 – 9.0	a'100: RD10247060 – 090	5906615 RD NS L PF 92
	latex, powdered, anatomic shape for single use	6.0 – 9.0	a'100: RD11247060 – 090	5906615 RD NS L PP 9N

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 I 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.

Date and place of issue:
24.06.2020, Kraków

MERCATOR MEDICAL S.A.
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Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieścia w Krakowie,
XI Wydział Gospodarczy KRS, KRS: 0000036244
Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
NIP: 677-10-36-424, REGON: 350967107
Numer BDO: 000056063
-6-

Signed on the behalf of the Manufacturer:

Wojciech Hercka
Product Documentation Manager