MERCATOR

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
santex® powdered	latex, powdered, smooth, for single use	XS (5-6) - XL (9-10)	a'100: RD11010001-05
	latex, powdered, textured, for single use	XS (5-6) - XL (9-10)	a'100: RD11086001-05
	latex, powdered, textured, for single use	XS (5-6) - XL (9-10)	a'100: RD11257001-05(1573)
Basic UDI-DI: 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 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 15223-1:2016, EN 1041:2008+A1:2013.

Products described above are also classified as Personal Protective Equipment in 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.

Products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. **(see Table 1)** issued by notified body **(see Table 1)**:

Products are also subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) or conformity to type procedure based on quality assurance of the production process (Module D), under surveillance of the notified body **(see Table 1).**

Table 1

Reference number	EU Type Certificate number	Notified Body – Module B	Notified Body – Module C2/D
RD11010001-05 RD11086001-05	2777/12773-01/E01-01	Module B: Satra Technology Europe Limited (2777)	Module C2: Satra Technology Europe Limited (2777)
RD11257001-05(1573)	2777/10468-04/E13-01	Module B: Satra Technology Europe Limited (2777)	Module D: Satra Technology Europe Limited (2777)

Date and place of issue:
04.01.2021, Kraków

Signed on the behalf of the Manufacturer:
J. Płaszewska
Joanna Płaszewska
Product Documentation Specialist

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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