

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
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, fingertip textured, for single use	XS (5-6) - XL (9-10)	a'100: RD11257001-05(1573)
Basic UDI-DI: 5906615 RD NS L PP 9N			
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: **(see Table 1).**

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: **(see Table 1).**

The products described above are 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	Compliance with European standards [MD]	Compliance with European standards [PPE]	EU Type Certificate number	Notified Body – Module B	Notified Body – Module C2/D
RD11010001-05 RD11086001-05	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	EN 420:2003+A1:2009 EN ISO 374-1:2016+A1:2018 EN ISO 374-2:2019 EN 16523-1:2015+A1:2018 EN 374-4:2013 EN ISO 374-5:2016	2777/12773-01/E01-01	Module B: Satra Technology Europe Limited (2777)	Module C2: Satra Technology Europe Limited (2777)
RD11257001-05(1573)	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	EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016	2777/10468-04/E13-01	Module B: Satra Technology Europe Limited (2777)	Module D: Satra Technology Europe Limited (2777)

Date and place of issue:
23.02.2022, Kraków

Signed on the behalf of the Manufacturer:

Leszek Garbacz
Leszek Garbacz
Product Documentation Manager