

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
nitrilex® classic	nitrile, powder-free, blue, for single use	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	nitrile, powder-free, white, for single use	XS (5-6) - XL (9-10)	a'50: RD30174001-05 a'100: RD30143001-05 a'200: RD30097001-05
	nitrile, powder-free, violet, for single use	XS (5-6) - XL (9-10)	a'100: RD30169001-05 a'200: RD30168001-05

classified as medical device class I according to Annex IX of the Council Directive 93/42/EEC meet the essential requirements of Annex I of the Council Directive 93/42/EEC amended by the Directive 2007/47/EC and comply with the European harmonized standards: EN 455, EN ISO 15223-1, EN 1041. Conformity assessment procedure performed according Annex I and Annex VII of the Council Directive 93/42/EEC amended by the Directive 2007/47/EC.

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. 2777/10015-03/E17-01 issued by notified body:

Satra Technology Europe Limited (2777)

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

Satra Technology Europe Limited (2777)

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:
30.09.2019, Kraków

MERCATOR MEDICAL S.A.
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tel. 12 66 55 400, fax 12 66 55 415
Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieście 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
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Signed on the behalf of the Manufacturer:



Wojciech Hercka
Product Documentation Manager