

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
Basic UDI-DI: 5906615 RD NS N PF 9C			

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 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:
 05.05.2020, Kraków

MERCATOR MEDICAL S.A.
 ul. Heleny Modrzejewskiej 30, 31-327 Kraków
 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

Signed on the behalf of the Manufacturer:


 Wojciech Hercka
 Product Documentation Manager

MERCATORMEDICAL

EU IZJAVA O SKLADNOSTI

Proizvajalec: **MERCATOR MEDICAL S.A.**
UL. H. MODRZEJEWSKIEJ 30
31-327 KRAKOW, POLSKA

Izjavlja na izključno svojo odgovornost, da so ne sterilne medicinske in zaščitne rokavice:

Znamka	Tip	Velikosti	Kataloške številke
nitrilex® classic	nitrilne rokavice, modre, brez pudra, za enkratno uporabo	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	nitrilne rokavice, bele, brez pudra, za enkratno uporabo	XS (5-6) - XL (9-10)	a'50: RD30174001-05 a'100: RD30143001-05 a'200: RD30097001-05
	nitrilne rokavice, vijolične, brez pudra, za enkratno uporabo	XS (5-6) - XL (9-10)	a'100: RD30169001-05 a'200: RD30168001-05
Basic UDI-DI: 5906615 RD NS N PF 9C			

v skladu z določbami Uredbe o medicinskih pripomočkih (EU) 2017/745 Evropskega parlamenta in Sveta z dne 5. aprila 2017 o medicinskih pripomočkih, so razvrščeni kot medicinski pripomoček razreda I v skladu s prilogo VIII Uredbe (EU) 2017/745 in ustrezajo harmoniziranim standardom: 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.

Izdelki so prav tako klasificirani kot osebna varovalna oprema, razvrščeni v kategorijo III in so v skladu z določbami Uredbe (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi in razveljavitvi Direktive Sveta 89/686/EGS ter ustrezajo harmoniziranim standardom: 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.

Izdelki ustrezajo osebni varovalni opremi, ki so predmet ugotavljanja skladnosti po EU – pregleda tipa (modul B) z izdanim certifikatom št. 2777/10015-03/E17-01 s strani priglašene organa:

Satra Technology Europe Limited (2777)

Bracetown Business Park, Clonee, Dublin 15, Dublin, Irska

Izdelki so skladni s tipom, ki temelji na notranji kontroli proizvodnje plus nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih (modul C2) pod nadzorom priglašene organa:

Satra Technology Europe Limited (2777)

Bracetown Business Park, Clonee, Dublin 15, Dublin, Irska

Datum in kraj izdaje:

05.05.2020, Krakow

Podpisano v imenu proizvajalca:

Wojciech Hercka

Vodja dokumentacije izdelkov