

**UE 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	Batch numbers
nitrilex® basic	nitrile, powder-free, dark blue, for single use	XS (5-6) - XL (9-10)	a'100 RD30105001-05 a'200 RD30084001-05
	nitrile, powder-free, violet, for single use	XS (5-6) - XL (9-10)	a'100 RD30106001-05 a'200 RD30098001-05

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 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:  
05.03.2019, Kraków

**MERCATOR MEDICAL S.A.**  
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tel. 12 66 55 400, fax 12 66 55 415  
Rejestracja: Sąd Rejonowy dla Krakowa - 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

Signed on the behalf of the Manufacturer:



Wojciech Hercka  
Product Documentation Manager