

EU DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLAND

declares under its sole responsibility that following products:

Product Name:	Product Description:	Sizes	Reference Numbers:	
			EO	GAMMA
COMFORT® POWDER-FREE	Sterile (EO/GAMMA) Powder-Free Latex Surgical and Protective Gloves	6.0	RC10003060	RC10004060
		6.5	RC10003065	RC10004065
		7.0	RC10003070	RC10004070
		7.5	RC10003075	RC10004075
		8.0	RC10003080	RC10004080
		8.5	RC10003085	RC10004085
		9.0	RC10003090	RC10004090
Classification:	Class IIa rule 6 as per Annex IX of the Council Directive 93/42/EEC and Regulation of Minister of Health of 5 November 2010 on the way of classification of medical devices			
UMDNS Code:	11883			
Notified Body:	DNV GL Presafe AS, No. 2460 Veritasveien 3 N-1363 Høvik, Norway			
EC Certificate No.:	11711-2017-CE-POL-NA-PS			

Conform to the applicable essential requirements of Annex I of the Medical Device Directive 93/42/EEC amended by the Directive 2007/47/EC. Conformity assessment procedure performed according to Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC amended by the Directive 2007/47/EC. These products comply with European harmonized standards: EN ISO 13485:2016, EN ISO 14791:2012, EN ISO 15223-1:2016, EN 1041:2008, EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN 556-1:2001|AC:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 11135-1:2007 (EO) or EN ISO 11137-1:2015 (Gamma), EN ISO 11137-2:2015 (Gamma), EN ISO 11138-2:2009 (EO), EN ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008 (EO), EN ISO 10993-10:2010.

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+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015, EN ISO 374-4:2019, 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. FI20/965656 issued by notified body:

SGS FIMKO OY (0598)

Takomotie 8, 00380, Helsinki, Finland

and are subject to the conformity assessment procedure based on quality assurance of the production process (Module D) under surveillance of the notified body:

SGS FIMKO OY (0598)

Takomotie 8, 00380, Helsinki, Finland

Date and place of issue:

14.12.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka

Product Documentation Manager

MERCATOR MEDICAL S.A.

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Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieście w Krakowie,
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Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
NIP: 677-10-36-424, REGON: 350967107
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