

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® POWDERED	Sterile (EO/GAMMA) Powdered Latex Surgical and Protective Gloves	6.0	RC11001060	RC11002060
		6.5	RC11001065	RC11002065
		7.0	RC11001070	RC11002070
		7.5	RC11001075	RC11002075
		8.0	RC11001080	RC11002080
		8.5	RC11001085	RC11002085
		9.0	RC11001090	RC11002090
		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. FI20/965655 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.
 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: 000036244
 Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
 NIP: 677-10-36-424, REGON: 350967107
 Numer BDO: 000056063