

## 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
<b>DERMAGEL® COATED</b>	Sterile (EO/GAMMA) Powder-Free Latex Surgical and Protective Gloves	6.0	RC10005060	RC10006060
		6.5	RC10005065	RC10006065
		7.0	RC10005070	RC10006070
		7.5	RC10005075	RC10006075
		8.0	RC10005080	RC10006080
		8.5	RC10005085	RC10006085
		9.0	RC10005090	RC10006090
<b>Classification:</b>	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			
<b>UMDNS Code:</b>	11883			
<b>Notified Body:</b>	<b>DNV GL Presafe AS, No. 2460</b> Veritasveien 3 N-1363 Høvik, Norway			
<b>EC Certificate No.:</b>	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, 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. FI20/965660 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,  
 XI Wydział Gospodarczy KRS, KRS: 0000036244

Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN  
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