MERCATOR

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:
DERMAGEL® MICRO	Sterile (GAMMA) Powder-Free Latex Surgical and Protective Gloves	6.0 6.5 7.0 7.5 8.0 8.5 9.0	RC10008060 RC10008065 RC10008070 RC10008075 RC10008080 RC10008085 RC10008090
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 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, 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. FI21/968137 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:
29.01.2021, Kraków

Signed on the behalf of the Manufacturer:

Wojciech Hercka
Product Documentation Manager

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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
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