

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® DUAL	Sterile (GAMMA) Powder-Free Double Latex Surgical Gloves with puncture identification system.	6.0	RC10046060
		6.5	RC10046065
		7.0	RC10046070
		7.5	RC10046075
		8.0	RC10046080
		8.5	RC10046085
	9.0	RC10046090	
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 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 standard: EN 420:2003+A1:2009.

Date and place of issue:
14.12.2020, Kraków

Signed on the behalf of the Manufacturer:



Wojciech Hercka

Product Documentation Manager

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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
NIP: 677-10-36-424, REGON: 350967107
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