

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:
SANTEX® POWDERED	Sterile (EO) Powdered Latex Surgical Gloves	6.0	RC11050060
		6.5	RC11050065
		7.0	RC11050070
		7.5	RC11050075
		8.0	RC11050080
		8.5	RC11050085
SANTEX® POWDER-FREE	Sterile (EO) Powder-Free Latex Surgical Gloves	9.0	RC11050090
		6.0	RC10051060
		6.5	RC10051065
		7.0	RC10051070
		7.5	RC10051075
		8.0	RC10051080
		8.5	RC10051085
		9.0	RC10051090
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, Nr 2460 Veritasveien 3 N-1363 Høvik, Norwegia		
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. This product complies with the following European harmonized standards: E 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, EN ISO 11138-2:2009, ISO 10993-1:2009|AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2010.

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 - 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
Numer BDO: 000056063