MERCATORMEDICAL

UE DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLSKA

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Batch numbers
santex® powdered	latex, powdered, for single use	XS (5-6) - XL (9-10)	a'100 RD11010001-05
	latex, powdered, textured, for single use	XS (5-6) - XL (9-10)	a'100 RD11086001-05

classified as medical device class I according to Annex IX of the Council Directive 93/42/EEC meet the essential requirements of Annex I of the Council Directive 93/42/EEC amended by the Directive 2007/47/EC and comply with the European harmonized standards: EN 455, EN ISO 15223-1, EN 1041. Conformity assessment procedure performed according Annex I and Annex VII of the Council Directive 93/42/EEC amended by the Directive 2007/47/EC.

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 374-1:2003 (excluding clause 5.3.2), EN 374-2:2003, EN 374-3:2003, EN 388:2003.

The products described above are identical to the Personal Protective Equipment, which is the subject of the EC Type Examination Certificate No. 8535 (Issue: 1, Extension 1) issued by:

SATRA Technology Centre (0321)
Wyndham Way, Kettering, Northamptonshire, NN16 8SD, Great Britain.

and are subject to the procedure specified in Article 11A of Council Directive 89/686/EEC under the supervision of:

SATRA Technology Centre (0321)
Wyndham Way, Kettering, Northamptonshire, NN16 8SD, Great Britain.

Date and place of issue:
17.04.2018, Kraków

MERCATOR MEDICAL
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Signed on the behalf of the Manufacturer:

Wojciech Hercka
Technical Documentation Specialist

Digitally signed by Chirtoacă Iurie
Date: 2021.08.16 13:13:46 EEST
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