

EC Certificate

Full Quality Assurance System

Certificate No.:
11711-2017-CE-POL-NA-PS Rev. 0.0

Project No.:
PRJC-542155-2016-PRC-POL

Valid Until:
27 December 2022

This is to certify that the quality system of:

Mercator Medical S.A.

ul. Heleny Modrzejewskiej 30
31-327 Kraków
Poland

For design, production and final product inspection/testing of:

Surgical gloves

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 27 December 2017



For:
DNV GL NEMKO PRESAFE AS

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	27-12-2017

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile and non-sterile powdered latex surgical gloves	comfort powdered	IIa
	santex powdered	
Sterile and non-sterile powder-free latex surgical gloves	comfort powder-free	IIa
	dermagel coated	
	dermagel dual	
	dermagel gyno	
	dermagel orthopedic	
	dermagel micro	
	santex powder-free	
Sterile and non-sterile powder-free non-latex surgical gloves	dermagel neopren	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

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Site Name	Address
Head office	ul. H. Modrzejewskiej 30, 31-327 Kraków, Poland
Division Brześć Kujawski	Stary Brześć Parcele 25E, 87-880 Brześć Kujawski, Poland
Division Brześć Kujawski	Stary Brześć Parcele 25D, 87-880 Brześć Kujawski, Poland

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate