

# CERTIFICATE

Management system as per  
**PN-EN ISO 13485:2016-04**  
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

**Mercator Medical S.A.**  
**ul. H. Modrzejewskiej 30, PL / 31-327 Kraków**

with the locations / sites according to the annex

applies a management system in line with the above standard for the following scope

**Production of medical gloves (examination gloves, surgical gloves),  
wound dressings, nonwoven disposable clothing and disposable surgical drapes.  
Purchase storage, distribution, domestic and international wholesale of medical gloves,  
wound dressings, nonwoven disposable clothing and disposable surgical drapes.**

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1642/4578/2018**  
Audit Report No. PL4578/2020

Valid from **01-04-2020**  
Valid until **31-03-2023**



Manager of Certification Body  
TÜV NORD Polska Sp. z o.o.

Katowice, 31-03-2020

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

[www.tuv-nord.pl](http://www.tuv-nord.pl)



AC 090  
QMS

# ANNEX

to Certificate Registration No.: **AC090 MD/1642/4578/2018**

**Mercator Medical S.A.**  
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| Certificate Registration No.       | Location  | Scope   |
|------------------------------------|---|---|
| <b>AC090 MD/1642/4578/2018-001</b> | Mercator Medical S.A.<br>Stary Brześć Parcele 25D/E,<br>PL / 87-880 Brześć Kujawski | Storage, distribution, domestic and international<br>wholesale of medical gloves, wound dressings,<br>nonwoven disposable clothing<br>and disposable surgical drapes. |
| <b>AC090 MD/1642/4578/2018-003</b> | Mercator Medical Kft Záhony<br>utca 7. A. ép. I. em.,<br>1037 Budapest, Węgry       | Wholesale of medical gloves and wound dressings,<br>nonwoven disposable clothing, disposable surgical<br>drapes and personal protective equipment.                    |

End of the List



Manager of Certification Body  
TÜV NORD Polska Sp. z o.o.

Katowice, 31-03-2020

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