

# Certificate

**mdc medical device certification GmbH**  
certifies that

**TECOmedical AG**  
**Gewerbestrasse 10**  
**4450 Sissach**  
**Switzerland**

with the locations listed in the attachment

for the scope

**manufacturing and distribution of immunological in vitro diagnostics and  
distribution of the following medical devices:  
closed drug transfer devices and the associated accessories**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

### EN ISO 13485

Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-02-23
Valid until	2025-03-31
Registration no.	D1415400007
Report no.	P22-01763-253544
Stuttgart	2023-02-23



Head of Certification Body



**Attachment of the certificate**

**No. D1415400007**

date 2023-02-23

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<b>Location</b>	<b>Scope</b>
TECOmedical AG Gewerbestrasse 10, 4450 Sissach Switzerland	manufacturing and distribution of immunological in vitro diagnostics and distribution of the following medical devices: closed drug transfer devices and the associated accessories
TECOmedical GmbH Wasserbreite 57, 32257 Bünde Germany	distribution of immunological in vitro diagnostics and distribution of the following medical devices: closed drug transfer devices and the associated accessories



Head of Certification Body