

Certificate

We hereby certify the company

TECOmedical AG
Gewerbestrasse 10
4450 Sissach
Switzerland

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in 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

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-05-14
Valid until 2025-03-31

Registration No. D1415400008
Report No. P23-01623-286476

Stuttgart, 2024-05-14



Certification Body



Sites included in the certification:

Location	Scope
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 Marie-Curie-Straße 1, 53359 Rheinbach Germany	distribution of immunological in vitro diagnostics and distribution of the following medical devices: closed drug transfer devices and the associated accessories

Stuttgart, 2024-05-14



Certification Body