

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1546485-1
Certificate Holder: Medical Technology Promedt
Consulting GmbH
Ernst-Heckel-Str. 7
66386 St. Ingbert
Germany

Scope: Provision of regulatory affairs services for active and non-active medical devices according to Regulation (EU) 2017/745 and in vitro diagnostic medical devices according to Regulation (EU) 2017/746.
Authorized representative for manufacturers of active and non-active medical devices and in vitro diagnostic medical devices according to article 11 Regulation (EU) 2017/745 and article 11 Regulation (EU) 2017/746.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1165133-40
Effective date: 2025-01-22
Expiry date: 2028-01-21
Issue date: 2025-01-17
Replaces certificate SX 1546485-1 issued 2023-02-21



Dipl.-Ing. (FH) Bastian Pfeiffer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

© TÜV, TÜEV and TUV are registered trademarks. Utilisation and application requires prior approval.