

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

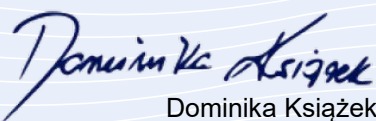
Registration No.: SX 2320977-1
Certificate Holder: SP Medical A/S
Møllevvej 1
4653 Karise
Denmark

Scope: Design and development, manufacture and distribution of sterile guide wires and sterile devices used for mixing medical products, DivibaX.
Manufacture, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according customer request.

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.: 84989393-20
Effective date: 2026-01-29
Expiry date: 2027-11-06
Issue date: 2026-01-29
Replaces certificate SX 2320977-1 issued 2024-10-28.

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


Dominika Książek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2320977-1
Certificate Holder: SP Medical A/S
Møllevvej 1
4653 Karise
Denmark

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SP Medical A/S Møllevvej 1 4653 Karise Denmark	Design and development, manufacture and distribution of sterile guide wires and sterile devices used for mixing medical products, DivibaX. Manufacture, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according customer request.
/02	SP Medical Sp. z o.o. ul. Ceramiczna 2 98-220 Zduńska Wola Poland	Design and development, manufacture and distribution of sterile guide wires and sterile devices used for mixing medical products, DivibaX. Manufacture, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according customer request.
/03	SP Medical Sp. z o.o. Stawiszczce 4 98-200 Sieradz Poland	Manufacture, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according customer request.

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