Certificate

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

Registration No.:	SX 2320977-1
Certificate Holder:	SP Medical A/S Møllevej 1 4653 Karise Denmark
Scope:	Design and development, production, distribution and final inspection of sterile guide wires and sterile devices used for collection of human specimens or mixing medical products DivibaX. Production, 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.:	84975201-50
Effective date:	2024-11-07
Expiry date:	2027-11-06
Issue date:	2024-10-28

Replaces certificate SX 2320977-1 issued 2021-11-08

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland® Precisely Right.

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Quality Management System
EN ISO 13485:2016
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Registration No.: SX 2320977-1

Certificate Holder: SP Medical A/S
Møllevej 1
4653 Karise
Denmark

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SP Medical A/S Møllevej 1 4653 Karise Denmark	Design and development, production, distribution and final inspection of sterile guide wires and sterile devices used for collection of human specimens or mixing medical products DivibaX. Production, 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, production, distribution and final inspection of sterile guide wires and sterile devices used for collection of human specimens or mixing medical products DivibaX. Production, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according customer request.

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