Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2320977-1

Organization:
SP Medical A/S
Møllevej 1
4653 Karise
Denmark

Scope:
Design and development, manufacture, distribution and final inspection of sterile guide wires and sterile devices used for mixing medicinal products – Divibax.
Production, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according to 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.: 84953052-20
Effective date: 2021-05-25
Expiry date: 2021-11-06
Issue date: 2021-05-21

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierstelle

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

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The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	SP Medical A/S Møllevej 1 4653 Karise Denmark	Design and development, distribution of sterile guide wires and sterile devices used for mixing medicinal products – Divibax. Production, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according to customer request.
/02	SP Medical Sp. z.o.o. ul. Ceramiczna 2 98-220 Zduńska Wola Poland	Design and development, manufacture, distribution and final inspection of sterile guide wires and sterile devices used for mixing medicinal products – Divibax. Production, filling, assembly, packaging, coating of injection molded plastic and metal parts to be used for medical devices according to customer request.

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