

Certificate



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, production, distribution and final inspection of sterile guide wires and sterile devices used for 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.: 84956485-20
Effective date: 2021-11-08
Expiry date: 2024-11-06
Issue date: 2021-11-08

A blue ink signature is written over a circular seal. The seal contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifizierungsstelle'.

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2320977-1

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

The scope of certification includes the following additional sites:

| No. | Facility | Scope |
|-----|--|---|
| /01 | SP Medical A/S Møllevvej 1 4653 Karise Denmark | Design and development, distribution of sterile guide wires and sterile devices used for 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 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. |

Report No.: 84956485-20
Effective date: 2021-11-08
Expiry date: 2024-11-06
Issue date: 2021-11-08



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

