# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 2320977-1

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

Products: - Sterile Accoat Standard Guide Wires.

For the following devices, the scope only covers the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile devices used for mixing medicinal products – Divibax.

Replaces EC Certificate number HD 2320977-1 issued on 2021-05-21

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84953048-20

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

| No. | Location | Product groups manufactured |
|---|---|---|
| /01 | SP Medical A/S<br>Møllevej 1<br>4653 Karise<br>Denmark | Activity: Design. |
| /02 | SP Medical Sp. z.o.o.<br>ul. Ceramiczna 2<br>98-220 Zduńska Wola<br>Poland | Activity: Design, manufacture and final inspection. |

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