

Certificate

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

Registration No.: SX 2774922-1
Certificate Holder: SP Meditec A/S Karise
Møllevvej 1
DK-4653 Karise
Denmark
Scope: Manufacture, filling, assembly and packaging of injection molded plastic and metal parts for use in medical devices according to customer specifications.

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.: 84993636-20
Effective date: 2026-07-06
Expiry date: 2027-11-06
Issue date: 2026-07-06
Replaces certificate SX 2320977-1 issued 2026-05-28

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


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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SP Meditec A/S Karise Møllevvej 1 DK-4653 Karise Denmark	Manufacture, filling, assembly and packaging of injection molded plastic and metal parts for use in medical devices according to customer specifications.
/02	SP Meditec Sp. z o.o. ul. Ceramiczna 2 98-220 Zduńska Wola Poland	Manufacture, filling, assembly and packaging of injection molded plastic and metal parts for use in medical devices according to customer specifications.
/03	SP Meditec Sp. z o.o. Stawiszcz 4 98-200 Sieradz Poland	Manufacture, filling, assembly and packaging of injection molded plastic and metal parts for use in medical devices according to customer specifications.

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