

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1010032-1


Organization: Löwenstein Medical Technology
GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Germany

Scope: Design and Development, Production, Distribution and Servicing of active Medical Devices, Patient Interfaces and Software for Diagnosis and Therapy of Respiratory related Diseases

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.: 1125103-40
Effective date: 2023-05-22
Expiry date: 2026-05-21
Issue date: 2023-05-19




Dipl.-Ing. F. Schwingen
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Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Löwenstein Medical Technology GmbH + Co. KG Kronsaalsweg 40 22525 Hamburg Germany	Design and Development, Production, Distribution and Servicing of active Medical Devices, Patient Interfaces and Software for Diagnosis and Therapy of Respiratory related Diseases
/02	c/o Löwenstein Medical Technology GmbH + Co. KG Südenstr. 42 76135 Karlsruhe Germany	Design and Development

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