

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1762136-1

Organization: Stryker Leibinger GmbH & Co. KG
Bötzingen Str. 41
79111 Freiburg
Germany


Scope: Design and development, manufacture, distribution, installation and service of:


- systems for computer assisted surgery including software, instruments, equipment and system elements
- non-active implant systems for fixation and distraction, instruments and components for CMF-, Neuro-, ENT and orthopedic surgery
- Connectable system elements for HF surgery.

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.: 1090704-10
Effective date: 2022-06-09
Expiry date: 2024-10-20
Issue date: 2022-06-09




Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

A circular seal for TÜV Rheinland LGA Products GmbH, featuring the company logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifizierungsstelle'.

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Stryker Leibinger GmbH & Co. KG Bötzing Str. 41 79111 Freiburg Germany	Design and development, manufacture, distribution, installation and service.
/02	c/o Stryker Leibinger GmbH & Co. KG Josef-Lang-Str. 22 78570 Mühlheim Germany	Manufacture and service of non-active implant systems, instruments and components for the CMF-, Neuro-, ENT- and orthopedic surgery and connectable system elements for HF surgery.
/03	c/o Scopis GmbH Heinrich-Heine-Platz 10 10179 Berlin Germany	Design and development of systems and system elements for computer-assisted surgery.
/04	c/o Stryker Leibinger GmbH & Co. KG Riegeler Str. 12 79111 Freiburg Germany	Supplier management and purchasing.

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The scope of certification also covers the following:

/05	c/o Stryker Leibinger GmbH & Co. KG Bötzingen Str. 39 79111 Freiburg Germany	Manufacturing of systems, instruments and system elements for computer assisted.
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