

Certificate

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

Registration No.: SX 1762136-1

Certificate Holder: Stryker Leibinger GmbH & Co. KG
Bötzing 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.: 1161150-10
Effective date: 2024-10-21
Expiry date: 2027-10-20
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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	c/o Stryker Leibinger GmbH & Co. KG Bötzingen 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 Stryker Leibinger GmbH & Co. KG Riegeler Str. 12 79111 Freiburg Germany	Customer service and administration
/04	c/o Stryker Leibinger GmbH & Co. KG Bötzingen Str. 39 79111 Freiburg Germany	Manufacturing of systems, instruments and system elements for computer assisted
/05	c/o Stryker Leibinger GmbH & Co. KG Bötzingen Str. 31 79111 Freiburg Germany	Warehouse and archive (storage location)

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

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Approval Information				
Group	Approval Role	Name	Date	Vote
Instruments - Regulatory - Freiburg - All Products	Project Manager	Eckert Lilian	2024-10-01 12:45:54.0	Approve
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