

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Stryker Leibinger GmbH & Co. KG
Bötzing Str. 41
79111 Freiburg
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

(Scope see attachment)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-08-17
Certificate Registration No.: SX 60140732 0001
An audit was performed. Report No.: 21199179 015
This Certificate is valid until: 2022-08-16

Certification Body



Date 2019-08-05



D. Wiedemuth
Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60140732 0001
Report No.: 21199179 015

Organization: Stryker Leibinger GmbH & Co. KG
Bötzing Str. 41
79111 Freiburg
Deutschland

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

Site included:


Stryker Leibinger GmbH & Co. KG
Josef-Lang-Straße 22
78568 Mühlheim-Stetten, Germany

Activities: 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.

Certification Body



Date: 2019-08-17


Dipl.-Ing. (FH) D. Wiedemuth