

**Business Stream Products  
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Stryker Endoscopy, a Division of  
Stryker Corporation  
5900 Optical Court  
SAN JOSE CA 95138  
USA

## Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date September 20, 2018

**Application for** : QMS  
**Certificate No.** : SX 60132127 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : EN ISO 13485:2016

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in  
accordance with the above mentioned requirements.Enclosed please find the certificate  
No. SX 60132127 0001.

Kind regards

Certification body

Dipl.-Ing. S. Pane



Test sample: no, documentation available

TÜV Rheinland  
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Board of Management

Dipl.-Ing.  
Jörg Mähler, SpokesmanDipl.-Kfm.  
Dr. Jörg SchlösserChairman of the  
Supervisory BoardDipl.-Ing.  
Ralf SchellerNuremberg HRB 26013  
VAT No.: DE 811835490

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Stryker Endoscopy, a Division of  
Stryker Corporation  
5900 Optical Court  
San Jose CA 95138  
USA**

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

**(see attachments for scope and additional facility)**

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: 2018-10-02  
Certificate Registration No.: SX 60132127 0001  
An audit was performed. Report No.: 31792498 005  
This Certificate is valid until: 2021-08-24

Certification Body



Date 2018-09-20



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

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60132127 0001  
**Report No.:** 31792498 005

**Organization:** Stryker Endoscopy, a Division of  
Stryker Corporation  
5900 Optical Court  
San Jose CA 95138  
USA

**Scope:**

Design and Development, Manufacture, Distribution and Service of:  
Anchors, Arthroscopic Blades, Arthroscopic Manual Instruments, Arthroscopic Shaver Systems, Arthroscopy Pumps and Tube Sets, Articulating Laparoscopes, Cannulaes, Control Systems, Electrocautery Probes, Electrosurgical Consoles and Probes, Endoscopes, Endoscopic Cameras, Adaptors, Image Processors, Endoscopic Hardware, Hysteroscopic Pumps, Illuminators, Insufflators, Laparoscopes, Laparoscopic Instruments, Orthopedic Internal Fixation Systems, Screws, Sliding Lock Atraumatic Graspers, Suction Irrigators, Surgical Bed Traction Systems, Urology and Gynecology Hardware Systems, Urology and Gynecology Scopes

**Certification Body**

 **DAkkS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

**Date:** 2018-10-02





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

**Attachment to  
Certificate**

**Registration No.:** SX 60132127 0001  
**Report No.:** 31792498 005

**Organization:** Stryker Endoscopy, a Division of  
Stryker Corporation  
5900 Optical Court  
San Jose CA 95138  
USA

**Scope:**

Additional Site:

Stryker Endoscopy  
a Division of Stryker Corporation  
5670 Greenwood Plaza Blvd,  
Greenwood Village, CO 80111, USA

Scope: Activities related to the Design and Development of  
Anchors, Arthroscopic Blades, Arthroscopic Manual  
Instruments, Orthopedic Internal Fixation Systems  
and Screws

**Certification Body**

 **DAkkS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

**Date: 2018-10-02**

