

**Business Stream Products  
Certification Department**



**TÜVRheinland®**

**LGA**

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Thomas Shafer  
Stryker Endoscopy, a Division of St  
Corporation, DBA Stryker Endoscopy  
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 April 16, 2020

**Application for** : Vollst. QMS, Anhang II MDD  
**Certificate No.** : HD 60148074 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : Richtlinie 93/42/EWG

Dear Mr. Shafer,

Your Quality Management System has been tested and found to be in  
accordance with the above mentioned requirements.

Enclosed please find the certificate  
No. HD 60148074 0001.

Kind regards

Certification body

Balazs Bozsik

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

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Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60148074 0001

**Report No.:** 31995194 003

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

**Products:** See the attachments for products covered by  
this registration

Replaces Approval, Registration No.: HD 60104853 0001

**Expiry Date:** 2025-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-05-27

**Date:** 2020-04-15



**Notified Body**



Balazs Bozsik

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.



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

**Attachment to  
Certificate**

**Registration No.:** HD 60148074 0001  
**Report No.:** 31995194 003

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

**Products:**

- Arthroscopic Instrumentation
- Arthroscopic shaver systems and blades
- Bone cutters
- Bone-resection orthopaedic reamers
- Dissection Scissors
- Endoscopic irrigation/aspiration pumps
- Endotherapy electrosurgical coagulator/cutter/  
/probe/diathermy systems
- Endotherapy trocars
- Flexible video laparoscopic systems
- Foot-switches, electrical
- General-Purpose Surgical Dissectors
- Illuminators
- Insufflation gas conditioning tubing sets
- Laparoscopic gas distention system
- Laparoscopic Instrumentation
- Operating room device management systems

(see next page for additional products)

**Date:** 2020-04-15



**Notified Body**

*Balazs Bozsik*

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

**Attachment to  
Certificate**

**Registration No.:** HD 60148074 0001  
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**Manufacturer:** Stryker Endoscopy,  
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**Products (continued):**

- Orthopaedic bone screws, non-bioabsorbable
- Orthopaedic instrumentation, kits
- Rigid arthroscopes
- Rigid cystoscopes
- Rigid endoscope adaptors, obturators, sheaths, cannulas, trocars
- Rigid hysteroscopes
- Rigid sinoscopes
- Rigid ureteroscopes
- Rigid video laparoscopes
- Scalpel blades
- Soft-tissue anchors, non-bioabsorbable
- Stone/foreign-body extraction sets
- Stopcocks
- Suction/Irrigation Systems
- Surgical drills
- Surgical drill guides

(see next page for additional products)

**Date: 2020-04-15**



**Notified Body**

*Bal Balazs*

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**Products (continued):**

- Surgical instrument sleeves
- Surgical irrigation/aspiration tubing sets
- Suture/needle passers, needle holders
- Tunnel plugs
- Universal electrosurgical diathermy system monopolar electrodes
- Universal hand-controlled electrosurgical diathermy system conducting units
- Urethrotomes

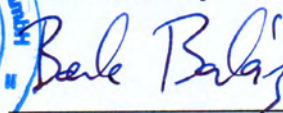
**Additional Scope of Certification:**  
Aspects of manufacture concerned with securing and  
maintaining sterile conditions  
**Products:**

- Endoscopic Instruments
- Urology and Gynecology Instruments
- Arthroscopy Tube Sets

**Date:** 2020-04-15



**Notified Body**



**Balazs Bozsik**