



TÜV Rheinland LGA Products GmbH • 90431 Nürnberg

Nathan Clark
Stryker Endoscopy
A Division of Stryker Corporation
5900 Optical Court
San Jose CA 95138
USA

Nhà sản xuất

Contact

Tel. +49 911 655-5225

Mail: service
@de.tuv.com

Date November 10, 2020

Application for: QMS

Certificate No. : SX 1192388-1

Requirement : EN ISO 13485:2016

Dear Nathan Clark,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the new certificate No. SX 1192388-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Balazs Bozsik
Certification body

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1192388-1

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, Cannulae, 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, Surgical Planning Software, Urology and Gynecology Hardware Systems, Urology and Gynecology Scopes, Operating Room Device Management Systems, Carts and Stands, Rigid Sinusopes

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.: 31995194.004

Effective date: 2020-12-01

Expiry date: 2023-11-30

Issue date: 2020-11-10



Balazs Bozsik

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Certificate

Quality Management System EN ISO 13485:2016

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5900 Optical Court
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The scope of certification also covers the following:

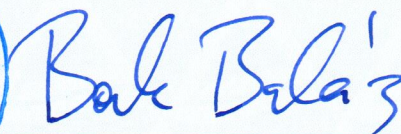
No.	Facility	Scope
/01	Stryker Endoscopy A Division of Stryker Corporation 5900 Optical Court San Jose CA 95138 USA	Design and Development, Manufacture, Distribution and Servicing
/02	Stryker Endoscopy 5670 Greenwood Plaza Blvd Greenwood Village CO 80111 USA	Design and Development

Report No.: 31995194.004

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