

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Stryker Instruments,
a Division of Stryker Corporation
4100 East Milham Avenue
Kalamazoo MI 49001-6797
USA**

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

(See attachment for scope and additional sites)

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: 2018-11-09
Certificate Registration No.: SX 60133914 0001
An audit was performed. Report No.: 31891182 002
This Certificate is valid until: 2021-10-29

Certification Body



Date 2018-11-09



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 60133914 0001
Report No.: 31891182 002

Organization: Stryker Instruments,
a Division of Stryker Corporation
4100 East Milham Avenue
Kalamazoo MI 49001-6797
USA

Scope:

For the Design and Development, Manufacture, Distribution, Installation, and Service of Automated Percutaneous Discectomy Systems, Bone Biopsy Systems, Bone Cement, Cement Mixing and Application Systems, Bone Cutting and Drilling Devices, Bone Mill Systems, Bone Preparation Systems, Cast Room Systems, Discography Systems, Electronic Surgical Sponge-Counters, Fragmentable Dressings, Head-Worn Lights Battery Powered, Large Bone Powered Surgical Systems, Percutaneous Cement and Systems, Personal Protection System, Pneumatic Bone Cutting and Drilling Devices, Pneumatic Tourniquet Systems, Pressure Monitor Systems, Pulsed Irrigation Systems, RF Generator Systems, RF Surgery Instruments, Short Term Bone Fixation Devices, Small Bone Powered Surgical Systems, Soft-Tissue Ultrasonic Surgical Systems, Vertebral Augmentation Systems, Waste Management Systems

Certification Body



Date: 2018-11-09

Songqi
S. Liu



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60133914 0001
Report No.: 31891182 002

Organization: Stryker Instruments,
a Division of Stryker Corporation
4100 East Milham Avenue
Kalamazoo MI 49001-6797
USA

Scope: Additional Facilities
Stryker Instruments,
a Division of Stryker Corporation
6201 South Sprinkle Rd., Portage, MI 49002 USA
Scope: Activities related to Manufacturing and Servicing

Stryker Instruments,
a Division of Stryker Corporation
6300 South Sprinkle Rd., Portage, MI 49002 USA
Scope: Activities related to Manufacturing and Distribution

Stryker Instruments,
a Division of Stryker Corporation
1901 Romence Rd., Portage, MI 49002 USA
Scope: Activities related to Administration

Certification Body



Date: 2018-11-09

S. Liu

