

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2247538-1

Organization: Stryker Instruments,
a division of Stryker Corporation
1941 Stryker Way
Portage MI 49002
USA

Scope: 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, Large Bone Powered Surgical Systems, Percutaneous Cement and Systems, Personal Protection Systems, 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, Wound Closure Devices, Hydrogen Peroxide-Ozone Sterilizers, Oxygen Concentrators, Biological Sterilization Indicators, Chemical / Physical Sterilization Process Indicator.

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.: 234188867-10
Effective date: 2022-05-25
Expiry date: 2024-10-31
Issue date: 2022-05-25



Aine Huang
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No.	Facility	Scope
/01	Stryker Instruments, a division of Stryker Corporation 1941 Stryker Way Portage MI 49002 USA	Activities related to Design and Development and Administration.
/02	Stryker Instruments, a division of Stryker Corporation 4100 E Milham Avenue Kalamazoo MI 49001-6797 USA	Activities related to Manufacturing and Distribution.
/03	Stryker Instruments, a division of Stryker Corporation 6201 South Sprinkle Road Portage MI 49002 USA	Activities related to Service.

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