EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2247538-1

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

Products:
Product Groups:
- Bone Cutting and Drilling Devices
- Soft-tissue Ultrasonic Surgical Systems

For the following devices, the scope only covers the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Fragmentable Dressings

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.

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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Signature Not Verified
Dokument podpisany przez Małgorzata Adamczyk
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.