ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC – C E R T I F I C A T E

Full Quality Assurance System

(Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

No. G1 11 03 73853 087

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield MA 02048
USA
(formerly: United States Surgical, a division of Tyco Healthcare Group LP)

EC-Representative:

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
Ireland

Product Category(ies):

Medical Instruments, Surgical Products and Drug Delivery Systems, Hemostatic Materials:
- **Surgical Suture Products, Pledgets and Retention Tapes**
- **Endoscopy Instruments and Accessories including Lubricant and Anti-Fog Solutions**
- **Surgical Staple, Clip Products and Accessories**
- **Manual Surgical Instruments**
- **Implantable Drug Delivery Systems and Accessories**
- **Implantable Wound Dressing Materials**
- **Detector Probes for use with Radiation Detection Instrumentation**
- **Minimally Invasive Breast System and Accessories**
- **Ultrasonic Surgical Devices and Accessories**
- **Biofragmentable Anastomotic Rings and Accessories**
- **Suction / Irrigation Devices and Accessories**
- **Arthroscopy Implants, Instruments and Accessories**
- **Bone Wax**
- **Temporary Cardiac Pacing Lead**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory.
See also notes overleaf.

Report No.: 71384433

Valid from: 2011-04-17
Valid until: 2016-04-16

Date: 2011-04-12

Hans-Heiner Junker

445493

TÜV SÜD PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

TÜV®

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Product Service

EC-CERTIFICATE
Full Quality Assurance System
(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)
No. G1 11 03 73853 087

Facility(ies):

Covidien
Sabanetas Industrial Park, Building 911-67,
Ponce PUERTO RICO 00731 USA
(formerly: U.S.S.C. Puerto Rico, Inc.)

Covidien
Carretera San Isidro km 17, Zona Franca de San Isidro,
Santo Domingo, DOMINICAN REPUBLIC
(formerly: Davis & Geck Caribe, Ltd.)

Covidien
19030 Libramiento, Boulevard Insurgentes,
22225 Tijuana, B.C., MEXICO
(formerly: Nellcor Puritan Bennett Mexico S.A. de C.V.)

Covidien Deutschland Manufacturing GmbH
Gewerbepark 1, 93333 Neustadt a.d. Donau, GERMANY
(formerly: Tyco Healthcare Deutschland GmbH)

Covidien
60 Middletown Avenue, North Haven CT 06473, USA
(formerly: United States Surgical, a division of Tyco Healthcare Group LP)

Covidien Medical Products (Shanghai)
Manufacturing L.L.C.
Building #10, 789 Puxing Road, 201114 Shanghai,
PEOPLE'S REPUBLIC OF CHINA

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