



Certificate

No. Q6 077608 0090 Rev. 00

Holder of Certificate: **Covidien llc**
15 Hampshire Street
Mansfield, MA 02048
USA

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

see scope of certificate

Certification Mark:



Scope of Certificate: Production and Sterilization of Absorbable and Non-Absorbable Surgical Suture Products and Endoscopy Instruments, Staple and Clip Products.

Production of:

-Active Medical Devices (Probes, Electrodes, Nerve Stimulators, EMG Tubes); Non-Active Medical Devices (Blades, Burs, Sheaths, ENT Packing, Dressings and Accessories, Disposable Surgical Instruments, Neurosurgical Paddies and Strips); Non-Active Implants (Typanostomy Ventilation Tubes and Ossicular Reconstruction Implants) for Area(s) of Otology, Rhinology, Sinus Endoscopy, Laryngology, Ophthalmology, Neurology, Aesthetic Plastic Surgery, Obstetrics and Gynecology, Orthopedic, General Surgery.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 077608 0090 Rev. 00

Report No.: 72166557

Valid from: 2022-01-24

Valid until: 2024-12-04

Date, 2022-01-24

Christoph Dicks
Head of Certification/Notified Body