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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 074735 0083 Rev. 00

Manufacturer:

Covidien llc

15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): Medical Devices for Wound Care, Wound Closure, Cardio-Thoracic, Cardio-Thoracic Drainage, Respiratory, Suction, Aspiration, Blood Collection, Gastro-Intestinal Management, Urology, Vascular Access, Enteral Feeding, Enteral Access, Needles, Syringes, Thermometry, Maternity Care, Foley Catheters, Foley Catheter Trays, O.R. Suction, Surgical Suction, Oxygen Delivery, Urine Meter, and Vascular Compression Devices

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.: 713175516

Valid from: 2020-02-28

Valid until: 2024-05-26

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body