Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 077790 0060 Rev. 00

Manufacturer:

Covidien LLC
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies):

Oximetry and Capnography Monitor Systems Temperature Monitor Systems, Patient Warming Device Systems, Disposable Airway Management Devices, Tracheal Tubes, Tracheostomy Tubes, Speaking Valves, and Intubating Stylets, Ventilator Systems and Patient Interface Circuit Systems, EEG Monitoring Systems, Breathing Therapy and Humidification, Heated Inspiratory Line Humidifiers, Multi-patient Physiologic Monitoring System and Data Analytics Software, Gastrointestinal Measurement and Dilation System, Electrosurgical Diathermy System Electrode.

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.: 72145607

Valid from: 2020-06-29
Valid until: 2024-05-26

Date, 2020-06-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany