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

TÜV SÜD 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 15 10 77790 028

Manufacturer:
Covidien llc
15 Hampshire Street
Mansfield MA 02048
USA

EC-Representative:
Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
IRELAND

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

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.: 72102885

Valid from: 2016-02-19
Valid until: 2020-06-30

Date, 2016-02-19

Stefan Preiß

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

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Facility(ies):

Covidien
6135 Gunbarrel Avenue, Boulder CO 80301, USA

Covidien
Avenue Henequen No. 1181, Park Industrial Salvarcar, 32573
Ciudad Juarez, Chihuahua, MEXICO

Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C.,
MEXICO

Covidien
Michael Collins Road, Mervue, Galway, IRELAND

Mallinckrodt Medical
Cornamaddy, Co. Westmeath, Athlone, IRELAND

Covidien llc
117 Moo 2, Petchkasem Road, Sampran, Nakorn-Pathom 73110,
THAILAND

Covidien
2101 Faraday Avenue, Carlsbad CA 92008, USA

Mallinckrodt Dar S.r.l.
Via G. Bove, 2/4/6/8, 41037 Mirandola (MO), ITALY

Covidien Ireland Limited
Tullamore Business and Technology Park, Srah, Tullamore, Co.
Offaly, IRELAND

Covidien Deutschland Manufacturing GmbH
Gewerbepark 1, 93333 Neustadt/ Donau, GERMANY

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