




America

CERTIFICATE

No. QS6 077790 0056 Rev. 03

Certificate Holder: Covidien LLC
15 Hampshire Street
Mansfield MA 02048
USA

Certification Mark:



Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F005456

Effective Date: 2021-06-14

Expiry Date: 2022-06-14

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Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Overall Scope Statement:

Design and Development, Production, and Distribution of Oximetry and Capnography Monitors and Sensors, Temperature Monitors and Disposables, Patient Warming Devices and Disposables, Tracheal and Tracheostomy Systems, Disposable Airway Management Devices, Ventilator Systems, Manifolds, Pressure Tubing, Suction Systems, EEG Monitoring Systems, Breathing Therapy and Humidification, Heated Inspiratory Line Humidifiers, Multi-Patient Physiologic Monitoring Systems and Data Analytics Software, Gastrointestinal Measurement and Dilation System; Service of Oximetry and Capnography Monitors, Patient Warming Devices, Multi-Patient Physiologic Monitoring Systems and Data Analytics Software, Gastrointestinal Measurement and Dilation System, Dialysis Devices, Ventilator Systems, and Electrosurgical Devices

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- Facility(ies):**
- Covidien LLC
15 Hampshire Street, Mansfield MA 02048, USA
 - Covidien
6135 Gunbarrel Avenue, Boulder CO 80301, USA
 - Covidien
2101 Faraday Avenue, Carlsbad CA 92008, USA
 - Covidien
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C., MEXICO
 - Mallinckrodt Medical
Cornamaddy, Co. Westmeath, Athlone, IRELAND
 - Covidien
Michael Collins Road, H91 W9N4 Mervue, Galway, IRELAND
 - Covidien
Avenue Henequen No. 1181, Park Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, MEXICO
 - Mallinckrodt Dar S.r.l.
Via G. Bove, 2/4/6/8, 41037 Mirandola (MO), ITALY
 - Covidien
2800 Airwest Blvd Suite 160, Plainfield IN 46168, USA

- Facility Scopes:**
- Covidien LLC**
15 Hampshire Street, Mansfield MA 02048, USA
Management of Service of Oximetry and Capnography Monitors, Patient Warming Devices, Multi-Patient Physiologic Monitoring Systems and Data Analytics Software, Gastrointestinal Measurement and Dilation System, Dialysis Devices, Ventilator Systems, and Electrosurgical Devices; Management of Design and Development, Production, and

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Distribution of Oximetry and Capnography Monitors and Sensors, Temperature Monitors and Disposables, Patient Warming Devices and Disposables, Tracheal and Tracheostomy Systems, Disposable Airway Management Devices, Ventilator Systems, Manifolds, Pressure Tubing, Suction Systems, EEG Monitoring Systems, Breathing Therapy and Humidification, Heated Inspiratory Line Humidifiers, Multi-Patient Physiologic Monitoring Systems and Data Analytics Software, Gastrointestinal Measurement and Dilation System
 REPs Facility ID: F005456

Covidien

6135 Gunbarrel Avenue, Boulder CO 80301, USA

Design and Development of Oximetry Monitors and Sensors, Temperature Monitoring Sensors and Disposables, Patient Warming Devices and Disposables, Tracheal and Tracheostomy Systems, Disposable Airway Management Devices, Suction Systems, EEG Monitoring Systems, Heated inspiratory Line Humidifiers, Breathing Therapy and Humidification, and Multi-patient Physiologic Monitoring Systems and Data Analytics Software; Production and Service of Multi-Patient Physiologic Monitoring Systems and Data Analytics Software
 REPs Facility ID: F002058

Covidien

2101 Faraday Avenue, Carlsbad CA 92008, USA

Design, Development and Post-Market Surveillance of Ventilator Systems; Service of Ventilator Systems, Dialysis Devices, and Electrosurgical Devices
 REPs Facility ID: F002108

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Covidien

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

Production and Distribution of Sensors, (Flow, Oximetry),
Cables, Respiratory Products (Sensors and CO2 Detectors),
Silicone Products / CPAP Nasal Cannula, Patient Warming
Devices

REPs Facility ID: F002054

Mallinckrodt Medical

Cornamaddy, Co. Westmeath, Athlone, IRELAND

Design, Development and Production including Sterilization
of Tracheal and Tracheostomy Systems, Disposable Airway
Management Devices

REPs Facility ID: F001266

Covidien

Michael Collins Road, H91 W9N4 Mervue, Galway, IRELAND

Production of Ventilator Systems, Oximetry Systems and related
Sensors, Gastrointestinal Measurement and Dilation Systems

REPs Facility ID: F002117

Covidien

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

Production of Temperature Probes, Tracheal and Tracheostomy
Tubes, Disposable Airway Management Devices, Respirator
Tubing Sets, Extension Tubing, Molded Components for
Tracheal and Tracheostomy Medical devices, Capnography
Accessories and Gastrointestinal Measurement and Dilation
Catheters

REPs Facility ID: F002113

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Mallinckrodt Dar S.r.l.

Via G. Bove, 2/4/6/8, 41037 Mirandola (MO), ITALY

Production of Disposable Airway Management Devices
and Disposables for Breathing Therapy and Humidification
REPs Facility ID: F001267

Covidien

2800 Airwest Blvd Suite 160, Plainfield IN 46168, USA

Service of Electrical Generator Systems, Radiofrequency Ablation and Lesioning Generators, Argon Gas Delivery Surgical Systems, Microwave Generators, Electrosurgical Vessel Sealing Systems, Portable Ventilators, Pulse Oximeters, Spirometers, Gastrointestinal Measurement and Dilation Hardware, and other Medical Devices used in the Treatment of Respiratory Illnesses, EEG Monitoring Equipment and Temperature Monitors, General Surgical Products for Woman's Health; Production of Accessories for Generator Systems, Respiratory Devices; Replication of Software to be used in Respiratory Devices; Distribution of all Devices within Certificate Scope
REPs Facility ID: F002109

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