ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 077790 0091 Rev. 01

Manufacturer:

Covidien LLC
15 Hampshire Street
Mansfield MA 02048
USA

SRN Manufacturer: Not available at issuance date of this certificate

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 077790 0091 Rev. 01

Report No.: 713257356

Preceding Certificate No.: G10 077790 0091 Rev. 00

Valid from: 2022-08-22
Valid until: 2027-02-21

Date of Initial Issuance: 2022-02-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-22

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	IIb
Device Group:	Z12030105 - PULMONARY VENTILATORS FOR HOSPITAL USE
Intended Purpose:	Adult and pediatric / neonatal ventilators provides respiratory support or mechanical ventilation. Intensive care ventilators - consumables removes particles and bacteria to minimize contamination. Intensive care ventilators - hardware provides temporary electrical energy to ventilator and/or compressor. Intensive care ventilators - hardware provides compressed air for ventilator. Intensive care ventilators - software embedded in ventilator monitors, processes and stores data to support ventilatory function.

Classification:	IIb
Device Group:	R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
Intended Purpose:	Tracheolaringostomy cannulas and kits, with cuff, provide tracheal access for airway management.

Classification:	IIb
Device Group:	R010503 - TRACHEOSTOMY INNER CANNULAS
Intended Purpose:	Tracheostomy inner cannulas with accompanying tracheostomy tube provide tracheal access for airway management.

Classification:	IIb
Device Group:	R010501 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
Intended Purpose:	Tracheolaringostomy cannulas and kits, without cuff, provide tracheal access for airway management.

Classification:	IIa
Device Group:	R010301 - ENDOTRACHEAL TUBES, CUFFLESS
Intended Purpose:	-/-

Classification:	IIa
Device Group:	R010302 - ENDOTRACHEAL TUBES, CUFFED
Intended Purpose:	./.

Classification:	IIa
Device Group:	R010380 - ENDOTRACHEAL TUBES - ACCESSORIES
Intended Purpose:	./.

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The validity of this certificate depends on conditions and/or is limited to the following:	none

Revision History:

Rev.	Dated	Report
00	2022-02-22	713209799

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