EU MDR Declaration of Conformity (DoC)

Manufacturer:	Covidien llc 15 Hampshire Street Mansfield, MA 02048 USA
Manufacturer SRN:	To be determined
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	To be determined
Notified Body:	Not Applicable
Conformity Assessment Certificate(s):	Not Applicable
Conformity Assessment Route:	Annex IV.
Risk Class:	Class I.
Classification rule:	Rule 5 Annex VIII.
Intended purpose:	The Respiflo™ respiratory exerciser is used by patients following thoracic surgery or in other conditions to assist the lungs in returning to normal functioning. The device contains graduations; however these are used for self evaluation / motivation of the patient and not for diagnostic use.

Statement:

We, Covidien llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Union Legislation	Declaration of Conformity Document Number
Not Applicable	Not Applicable

Place: Boulder, CO

Name: Yaara Basevitch

Title: Regulatory Affairs Director Respiratory Interventions

Signature:

Date: 24-feb-2021

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., GMDN)
	CFN		
Respiflo™ FS Respiratory Exerciser	8884717395	0763000B000013372	31266

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not Applicable	Not Applicable	Not Applicable

Revision History

See Document Management System (DMS).

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