

Manufacturer

Covidien Inc
15 Hampshire Street
Mansfield, MA 02048 USA
(formerly: Nellcor Puritan Bennett L.L.C., a
division of Tyco Healthcare Group LP)

Authorized European Representative

Covidien Ireland Limited
IDA Business & Technology Park
Tullamore, Ireland

Notified Body

TÜV SÜD Product Services GmbH
Ridlerstrasse 65
D-80339 Munich
Germany
0123

Declaration of Conformity

Document #/Revision #: 10073745 Rev. K

Product/Family Name: Oral/Nasal Tracheal Tube

Classification Rationale: Class IIa per Rule 5 of Annex IX

EU Conformity Assessment Route: Annex II excluding (4)

Standards Applied: Refer to ERM #10073744.

Start of CE Marking: 08/2008

Covidien Inc declares under our sole responsibility that the above product(s) to which this declaration relates, and which bear(s) the CE Marking, is (are) in conformity with the Essential Requirements of EC Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EC of the European Parliament and of the Council, concerning medical devices, which allows their free distribution, sale and circulation in the European Union (EU); they comply with the provisions of the defined regulatory requirements and which comply with the referenced standards, as stated above.

This declaration is made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (TGA) Medical Device Regulations 2002, relating to the devices stated in Schedule I of this document.

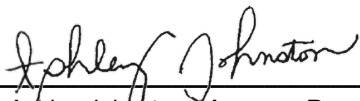
- All supporting documentation is retained by the manufacturer
- As required by the above Directive, this Declaration is supported by
 - EC Certificate: MDD Annex II excluding (4), G1 077790 0060 Rev. 00, Reference P/N 10069299, issued by TÜV SÜD Product Services GmbH, Ridlerstrasse 65, D-80339 Munich Germany, on 2020-06-29.
- This Declaration of Conformity is applicable to all of the medical devices referenced in Schedule I, manufactured by Covidien Inc and/or produced under its certified Quality System control. Products referenced in Schedule I can be traced by means of the related product identification referenced in the relevant labeling (i.e.: lot number, serial number, etc.).
- Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential requirements/principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

This Declaration shall be retained for a period of the lifetime of the medical device (LMD) + 1 year or minimum of 15 years once the record is obsoleted or superseded.

Date of Issue: March 2021

Place of Issue: Boulder, CO USA

Signature:



Name/Title

Ashley Johnston, Manager, Regulatory Affairs RI

Schedule 1
Declaration of Conformity for Oral/Nasal Tracheal Tubes

Medical Device Part Number	Description	Class/ Rule	UMDNS Code and Term	GMDN Code and Term
9320 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 2.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9325 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 2.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9335 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 3.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9336 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 3.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9342 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 4.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9345 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 4.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9350 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 5.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9360 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 5.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9365 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 6.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9366 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye, 6.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9370 E	Oral/Nasal Tracheal Tube Cuffless, Murphy Eye 7.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9430 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 3.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9440 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 4.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9450 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 5.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9460 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 6.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9465 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 6.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use

Medical Device Part Number	Description	Class/ Rule	UMDNS Code and Term	GMDN Code and Term
9475 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 7.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9480 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 8.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9485 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 8.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9495 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 9.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9500 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 10.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9555 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 5.5mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9570 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 7.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use
9590 E	Oral/Nasal Tracheal Tube Cuffed, Murphy Eye, 9.0mm	Ila	14085 – Tubes, Tracheal	14085 – Tracheal tube, general purpose, single use