Manufacturer	*Authorized European Representative*
Covidien llc 15 Hampshire Street Mansfield, MA 02048 USA (formerly: Nellcor Puritan Bennett L.L.C., a division of Tyco Healthcare LP)	Covidien Ireland Limited IDA Business & Technology Park Tullamore, Ireland

Người đại diện hợp pháp của cơ sở
CÔNG TY TNHH MEDTRONIC VIỆT NAM
Trần Thị Thanh Trà
Trưởng Bộ phận Chất lượng và Pháp chế

Digitally signed by CÔNG TY TNHH MEDTRONIC VIỆT NAM
Date: 2022.05.30 16:47:12 +07'00'

Declaration of Conformity

Document # **10066891 Revision H**

Product/Family Name: **Tracheal Tube Stylets (Non-Sterile)**

Classification Rationale: Class I per Rule 5 of Annex IX

EU Conformity Assessment Route: Annex VII

Standards Applied: Refer to Section 4 of Technical file # 10059273.

Start of CE Marking: 7th September 1995

Covidien llc 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
    - Quality System Certificate: Q5 18 02 77790 045, issued by TÜV SÜD Product Services GmbH, Ridlerstrasse 65, D-80339 Munich, Germany on 2018-03-01
- This Declaration of Conformity is applicable to all of the medical devices referenced in Schedule I, manufactured by Covidien llc 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: 26th March2018

Place of Issue: Athlone, IR

Signature: MARCH 29TH 2018

Name/Title Mike Aymami, Director, Regulatory Affairs

Schedule 1

Declaration of Conformity for Tracheal Tube Stylets - Non-Sterile

Medical Device Part Number	Description	Class / Rule	UMDNS Code and Term	GMDN Code and Term
116-06	Intubating Stylet	I / 5	14084 – Stylets, Tracheal Tube,	37469 – Stylet, Tracheal Tube – Single Use
116-10	Intubating Stylet	I / 5	14084 – Stylets, Tracheal Tube,	37469 – Stylet, Tracheal Tube – Single Use
116-14	Intubating Stylet	I / 5	14084 – Stylets, Tracheal Tube,	37469 – Stylet, Tracheal Tube – Single Use