Manufacturer	*Authorized European Representative*	*Notified Body*
Covidien llc 15 Hampshire Street, Mansfield, MA 02048 USA (formerly: Nellcor Puritan Bennett L.L.C., a division of Tyco Healthcare Group LP)	Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands	TÜV SÜD Product Services GmbH Ridlerstrasse 65 80339 Munich Germany 0123

Declaration of Conformity

Document #/Revision #: RE00285260 Rev. B

Product/Family Name: Intubating Stylets

Classification Rationale: Class IIa per Rule 5 of Annex IX

EU Conformity Assessment Route: Annex II excluding (4)

Standards Applied: Refer to Section 4 of Technical Documentation # RE00242733

Start of CE Marking: 09/1995

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
    - EC Certificate: MDD Annex II excluding (4), G1 077790 0060, Reference P/N 10069299, issued by TÜV SÜD Product Services GmbH, Ridlerstrasse 65, 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 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: 14 May 2021

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.31 09:47:26 EET
Reason: MoldSign Signature
Location: Moldova

Place of Issue: Boulder, CO USA

Signature: _____

Name/Title Ashley Johnston, Manager, Regulatory Affairs RI

Schedule 1
Declaration of Conformity for Intubating Stylets

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