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)	Covidien Ireland Limited IDA Business & Technology Park Tullamore, Ireland	TÜV SÜD Product Services GmbH Ridlerstrasse 65 D-80339 Munich Germany 0123

Declaration of Conformity

Document #/Revision #: 10130199, Rev F

Product/Family Name: Nellcor™ Portable SpO_2 Patient Monitoring System

Classification Rationale: Class IIb per Rule 10 of Annex IX

EU Conformity Assessment Route: Annex II

Standards Applied: Refer to Section 4 of Technical File #10127173

Start of CE Marking: 05/2014

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.

Covidien llc hereby declares that all medical devices referenced in Schedule I placed on the European Community market by the Company & its subsidiaries are compliant with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (commonly known as the EU RoHS Directive). They are RoHS compliant.

- All supporting documentation is retained by the manufacturer
- As required by the above Directive, this Declaration is supported by:
  - EC Certificate: MDD Annex II, G1 15 10 77790 028, issued by TÜV SÜD Product Services GmbH, Ridlerstrasse 65, D-80339 Munich Germany, on 2016-02-19
  - Quality System Certificate: ISO 13485:2016, Q5 18 02 77790 045, issued by TÜV SÜD Product Services GmbH, Ridlerstrasse 65, D-80339 Munich Germany on March 1, 2018
- 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 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: 28 March 2018

Place of Issue: Boulder, Colorado, USA

Signature: _____ MARCH 28TH 2018

Name/Title Michael Aymami, Director, Regulatory Affairs

Schedule 1
Declaration of Conformity for Nellcor™ Portable SpO_2 Patient Monitoring System

Medical Device Part Number	Description	Class/ Rule	UMDNS Code and Term	GMDN Code and Term
PM10N	Nellcor™ Portable SpO_2 Patient Monitoring System	IIb/10	17148 – Oximeters, Pulse	17148 – Oximeters, Pulse