# EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II & Annex VII)
(Following the provisions of the RoHS directive 2011/65/EU, Articles 7, 13 and Annex VI)

We

Manufacturer

**GE Healthcare Finland Oy**
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**FI-00510 Helsinki, Finland**

Manufacturing Sites

**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES**
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**Carlisle Medical Technologies (Dongguan) Co., Ltd.**
**No. 2, Xinhu Industrial Park, Qiaolong Road**
**Dengwu Village, Qiaotou Town**
**Dongguan**
**523533 Guangdong**
**China**

Declare under our sole responsibility that the class IIb and I devices:

**TruSignal® SpO2 Sensors and Interconnect Cables**

Oximeter, pulse

Probe, pulse oximeter, single use

Ref.: See addendum
GMDN Code: 17148, 31658
Classification rule (93/42/EC Annex IX): Rule 10

**Oxytip Pulse Oximetry (SpO2) accessories - Wraps and Tapes**

Electrode/transducer strap, reusable

Basic adhesive tape

Ref.: See addendum
GMDN Code: 35709, 16866
Classification rule (93/42/EC Annex IX): Rule 1

to which this declaration relates, are in conformity with the requirements of the medical devices directive 93/42/EEC which apply to them and with the requirements of the RoHS Directive 2011/65/EU, Article 4.

This conformity is based on the following elements:

- Information included in the documents:
  Technical File réf. : DOC1097590 of the product to which this declaration relates.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by VTT Industrial Systems (Notified Body no. 0537) on 8 May 2015 / Certificate N° VTT-C-11340-01-1004-543-15
- The following reference evidence that the TruSignal® SpO2 Sensors and Interconnect Cables as electrical devices used are in compliance with the RoHS directive for CE marking:
  - TruSignal product Family RoHS Compliance Report (DOC1514561)
- List of standards applied for CE marking (non-compliance to standards attributable to the above named devices are listed as applicable):

| | |
|---|---|
| EN ISO 14971: 2012 | Application of risk management to medical devices |
| ISO 80601-2-61:2011 | Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |
| ISO 9919:2009 | Pulse oximeters for medical use – Requirements |
| IEC 60601-1:2005 /C1:2006/C2:2007/ EN 60601-1:2006 | Medical Electrical Equipment, Part 1: General Requirements for Safety and Essential Performance |
| IEC 60601-1-2:2014 EN 60601-1-2:2015 | Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard Electromagnetic Disturbances – Requirements and Tests |
| IEC/EN 60601-1-6:2010 | General requirements for safety – Collateral standard: Usability |
| EN 1041: 2008 | Information supplied by the manufacturer of medical devices |
| EN 980: 2008 | Symbols for use in the labelling of medical devices |

| | |
|---|---|
| EN 10993-1: 2009 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity |
| EN ISO 10993-10:2009 | Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity |
| EN 50581:2012 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |

Helsinki, 02-January-2019

Rauno Ruoho
Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 27-July-2018.

## ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 27-July-2018

| PRODUCT | ID(model/ code) | GMDN Code | Class |
|---|---|---|---|
| TruSignal® SpO2 Finger Sensor | TS-F-D | 17148 | IIb |
| TruSignal® SpO2 Finger Sensor, GE connector | TS-F4-GE | 17148 | IIb |
| TruSignal® SpO2 Finger Sensor, GE connector | TS-F2-GE | 17148 | IIb |
| TruSignal® SpO2 Finger Sensor, Trusat connector | TS-F4-MC | 17148 | IIb |
| TruSignal® SpO2 Ear Sensor | TS-E-D | 17148 | IIb |
| TruSignal® SpO2 Ear Sensor, GE connector | TS-E4-GE | 17148 | IIb |
| TruSignal® SpO2 Ear Sensor, GE connector | TS-E2-GE | 17148 | IIb |
| TruSignal® SpO2 Ear Sensor, Trusat connector | TS-E4-MC | 17148 | IIb |
| TruSignal® SpO2 Wrap Sensor | TS-W-D | 17148 | IIb |
| TruSignal® SpO2 Sensitive Skin | TS-SE-3 | 17148 | IIb |
| TruSignal® SpO2 FingerTip Sensor | TS-SA-D | 17148 | IIb |
| TruSignal® SpO2 FingerTip Sensor, GE connector | TS-SA4-GE | 17148 | IIb |
| TruSignal® SpO2 FingerTip Sensor, Trusat connector | TS-SA3-MC | 17148 | IIb |
| TruSignal® SpO2 PediTip Sensor | TS-SP-D | 17148 | IIb |
| TruSignal® SpO2 PediTip Sensor, GE connector | TS-SP3-GE | 17148 | IIb |
| TruSignal® SpO2 PediTip Sensor, Trusat connector | TS-SP3-MC | 17148 | IIb |
| TruSignal® SpO2 Interconnect Cable with GE connector | TS-G3 | 17148 | IIb |
| TruSignal® SpO2 Interconnect Cable with Trusat connector | TS-M3 | 17148 | IIb |
| TruSignal® SpO2 Interconnect Cable with Ohmeda connector | TS-H3 | 17148 | IIb |
| TruSignal® SpO2 Interconnect Cable with Nicolay connector | TS-N3 | 17148 | IIb |
| TruSignal® INTEGR H SPO2 FINGER SENSOR | TS-F1-H | 17148 | IIb |
| TruSignal® INTEGR H SPO2 FINGER SENSOR | TS-F4-H | 17148 | IIb |
| TruSignal® INTEGR N SPO2 FINGER SENSOR | TS-F4-N | 17148 | IIb |

| | | | |
|---|---|---|---|
| TruSignal® INTEGR SPO2 H EAR SENSOR | TS-E4-H | 17148 | IIb |
| TruSignal® INTEGR N SPO2 EAR SENSOR | TS-E4-N | 17148 | IIb |
| TruSignal® INTEGR H SPO2 WRAP SENSOR | TS-W4-H | 17148 | IIb |
| TruSignal® SpO2 Allfit Sensor | TS-AF-10<br>TS-AF-25 | 31658 | IIb |
| TruSignal® SpO2 Adult/Pediatric Sensor | TS-AP-10<br>TS-AP-25 | 31658 | IIb |
| TruSignal SpO2 Adult Adhesive Wrap sensor | TS-AAW-10<br>TS-AAW-25 | 31658 | IIb |
| TruSignal SpO2 Pediatric Adhesive Wrap sensor | TS-PAW-10<br>TS-PAW-25 | 31658 | IIb |
| Replacement Headband Kit, OXY-E-XX | OXY-HB | 35709 | I |
| Foam Replacement Wrap, OXY-W | OXY-RWL | 35709 | I |
| OxyTip+(R) Wide Replacement Tape | OXY-RTW | 35709 | I |
| Infant Foam Sandal Wrap | OXY-SND | 35709 | I |
| Foam Replacement Wrap Small, OXY-SE-3 | OXY-RWS | 35709 | I |
| Foam Replacement Wrap Medium, OXY-SE-3 | OXY-RWM | 35709 | I |
| Bed sheet clip | OXY-BC-5 | 35709 | I |
| Allfit Replacement Tape, Blue | OXY-RT | 16866 | I |
| Allfit Replacement Tape, Bear | OXY-RTB | 16866 | I |