This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and General Safety and Performance Requirements.

1. Object of the declaration:

Product Name	Reusable Adult SpO2 Sensor
Product Type	SpO2 Sensor
Intended Purpose	These SpO2 sensors are for multi-patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring are required. Sensors are for use by professionally trained clinicians such as nurses, physicians, and EMS personnel for the treatment of patients in and out of a hospital, as well as during transport.
Product Part Number(s) and Descriptions	M1191B – Reusable Adult SpO2 Sensor M1191BL - Reusable Adult SpO2 Sensor
Product Options/Accessories Part Number(s) and Descriptions	None
Control Indicator	Starting Serial Number: 1621G90000 (M1191B) Starting Serial Number: 1621G87000 (M1191BL)
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	**37808** - Pulse oximeter probe, reusable

The object of the Declaration described above is in conformity with the following regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)**
Device Risk Classification	Class IIb, according to Annex IX, Rule 10
Conformity Assessment Path	Annex II excluding (4) of the MDD Council Directive 93/42/EEC concerning medical devices as amended by 2007/47/EC. Products to which this declaration relates are in conformity with Annex I Essential Requirements of the European Directive: Council Directive 93/42/EEC concerning medical devices as amended by 2007/47/EC.
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80335 München Germany ID No.: 0123
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. EN 60601-1:2006 + Cor. :2010 + A1:2013 Medical electrical equipment Part 1: General requirements for basic safety and essential performance EN ISO 80601-2-61:2011 Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment EN ISO 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 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

2. Additional information:

Manufacturer	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard-Str. 2 71034 Böblingen Germany
EU Authorized Representative	Not applicable
Quality Certificates Issued	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485:2016, Certificate no.: Q5 052098 0009 Rev. 01 EC Certificate, Certificate no.: G1 052098 0011 Rev. 00

Signature (signed for and on behalf of Philips Medizin Systeme Böblingen GmbH):

Date of Issue: 02-March-2021

Printed Name:
Hauke Schik

Place of Issue: 71034 Böblingen, Germany

Title: Head of Q&R, Patient Monitoring

A-M119B-97001-1-DoC-MDD

Date of Expiration 02-March-2023

Record Identification: A-M119B-97001-1_Attachment_A

PHILIPS

Attachment A to Declaration of Conformity SpO2 Sensors

Declaration of Conformity Document Number/Rev.:	A-M119B-97001-1, Rev G
Description of the change	Version ISO 80601-2-61:2017 2nd edition 2017-12 corrected version 2018-02 was published replacing former version ISO 80601-2-61:2011, First edition 2011-04-01. Testing was performed to show compliance to the latest revision of the ISO 80601-2-61 (2017+C1:2018)/EN ISO 80601-2-61:2019 Standard for the Philips FAST SpO2 Sensors. Furthermore, the expiration date of the Declaration of Conformity for the Reusable SpO2 Sensors (A-M119B-97001-1) is 02-March-2023 and with this attachment it will be extended until 25-May-2024 (this is also in accordance with the MDD EC Certificate G1 052098 0011 that expires on 26-May-2024).
Assessment:	There is no change to the intended purpose, no change of the design or performance specification, no software change, no label change, no change of material and no change to the packaging. Therefore, according to EU MDR Art. 120 (3), the change is considered non-significant.
Additional comment:	N/A

Signature (signed for and on behalf of Philips Medizin Systeme Böblingen GmbH):

Date of Issue: 30-Jun-2022

Printed Name:
Kavita Mayekar-Doornenbal

Place of Issue: 71034 Böblingen, Germany

Title:
Regulatory Affairs CoE Manager

Date of Expiration: 25-May-2024