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	Avalon Fetal Monitor
Product Type	Fetal/Maternal Monitor
Intended Purpose	The Philips Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A), and FM50 (M2705A) fetal/ maternal monitors are intended for: • noninvasive monitoring of fetal heart rates and movements. • noninvasive monitoring of maternal heart rates, maternal pulse rates, uterine activity, maternal noninvasive blood pressure, maternal oxygen saturation, and maternal temperature. • invasive monitoring of direct fetal heart rate, intrauterine pressure, and for displaying and recording of fetal and maternal electrocardiogram (ECG) (FM30 and FM50 only). • displaying, storing, and recording patient data and parameter values, and for generating alarms from fetal and maternal parameters. • transmitting patient data and parameter values to a patient information and surveillance system. • use by trained health care professionals. • use in antepartum testing areas, in labor and delivery rooms, and during postpartum recovery in the hospital environment. They are not intended for use in intensive care units or operating rooms. • monitoring in a bath or shower (Avalon CL cableless transducers Toco^{+} MP, Ultrasound, and ECG/IUP only). • transport situations in healthcare facilities, for healthcare facilities outside hospitals, such as doctors' offices, and for use in private households (FM20 and FM30 only). Avalon Fetal/Maternal Monitor FM20: Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters

	uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities. Avalon Fetal/Maternal Monitor FM30: Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, non-invasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities. Avalon Fetal/Maternal Monitor FM40: Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas. Avalon Fetal/Maternal Monitor FM50: Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, non-invasive blood pressure, pulse rate and temperature of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.
Product Part Number(s) and Descriptions	

Avalon Fetal Monitor FM20	M2702A
Avalon Fetal Monitor FM30	M2703A
Avalon Fetal Monitor FM40	M2704A

	Avalon Fetal Monitor FM50 — M2705A Avalon Toco+ MP Transducer — 867245 Avalon Ultrasound Transducer — 867246 Avalon ECG/IUP Transducer — 867247 Avalon Toco MP Transducer — 867248 Avalon Toco+ Transducer — 867249 Avalon CL Base Station — 866074 Avalon CL Toco+ MP Transducer — 866075 Avalon CL Ultrasound Transducer — 866076 Avalon CL ECG/IUP Transducer — 866077 Avalon CL Fetal & Maternal Pod — 866488
Product Options/Accessories Part Number(s) and Descriptions	None
Basic UDI-DI	Avalon Fetal Monitor FM20 — M2702A — 0884838BM578TQ Avalon Fetal Monitor FM30 — M2703A — 0884838BM578TQ Avalon Fetal Monitor FM40 — M2704A — 0884838BM578TQ Avalon Fetal Monitor FM50 — M2705A — 0884838BM578TQ Avalon Toco+ MP Transducer — 867245 — 0884838BM576TL Avalon Ultrasound Transducer — 867246 — 0884838BM576TL Avalon ECG/IUP Transducer — 867247 — 0884838BM576TL Avalon Toco MP Transducer — 867248 — 0884838BM576TL Avalon Toco+ Transducer — 867249 — 0884838BM576TL

	Avalon CL Base Station — 866074 — 0884838BM574TG Avalon CL Toco+ MP Transducer — 866075 — 0884838BM576TL Avalon CL Ultrasound Transducer — 866076 — 0884838BM576TL Avalon CL ECG/IUP Transducer — 866077 — 0884838BM576TL Avalon CL Fetal & Maternal Pod — 866488 — 0884838BM576TL
Control Indicator	SW Revision: L.3
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	**37796** (M2702A, M2703A, M2704A, M2705A) - Cardiotocograph **38480** (866074) – Cardiotocography telemetric monitoring system receiver **38481** (866075, 866076, 866077, 866488) - Cardiotocography telemetric monitoring system transmitter **36553** (867245, 857247, 867249) - Patient monitoring system module, multifunction **41917** (867246) - Foetal doppler system probe **37258** (867248)- Cardiotocograph transducer

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 based on Annex IX and 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. Refer to Attachment A.

EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)**
Device Classification	Category 8, medical device, according to Annex I
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 IEC 63000: 2018 - Technical Documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

2. Additional information:

Manufacturer	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard-Str. 2 71034 Böblingen GERMANY SRN: DE-MF-000006026
EU Authorized Representative	Not applicable

	Philips Medizin Systeme Böblingen GmbH is located in the European Union.
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

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

Printed Name:
Arti Arvind

Title:
Regulatory Affairs Manager

Date of Issue: 26-AUG-2021

Place of Issue:
71034 Böblingen, Germany

A-M2703-97008

Date of Expiration: 26-MAY-2024

3. Attachment A

Standards and/or Common Specifications

Quality System	
ISO 13485:2016 **EN ISO 13485:2016**	Medical devices – Quality management systems – Requirements for regulatory purposes
Risk Management	
ISO 14971:2019 **EN ISO 14971:2019**	Medical devices. Application of risk management to medical devices.
Software life cycle	
IEC 62304:2006 + A1:2015/ **EN 62304:2006 + A1:2015**	Medical device software. Software life cycle processes.
General Safety Standard	
IEC 60601-1:2005 + A1:2012 **EN 60601-1:2006 +A1:2013**	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014 **EN 60601-1-2:2015**	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010 + A1:2013 **EN 60601-1-6:2010 + A1:2015**	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006 + A1:2012 **EN 60601-1-8:2007 + A1:2013**	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60529:1989 **+ A1:1999 +A2:2013** **EN 60529:1991** **+ A1:2000 + A2:2013**	Degrees of protection provided by enclosures (IP Code)

Particular Standards	
IEC 60601-2-27 :2011 + COR1:2012 **EN 60601-2-27:2014**	Medical Electrical Equipment – Part 2-27: Particular requirements for the safety, including essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2009 **EN 80601-2-30:2010**	Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 80601-2-49:2018 **EN 60601-2-49:2015**	Medical Electrical Equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-56:2017 **EN ISO 80601-2-56:2017**	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011 **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 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices
Biocompatibility Standards	
ISO 10993-1:2009 **EN ISO 10993-1: 2009 + AC:2010**	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 **EN ISO 10993-5: 2009**	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 **EN ISO 10993-10: 2013**	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-18:2005 **EN ISO 10993-18: 2009**	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
RoHS	
EN IEC 63000:2018	Technical Documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.