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EU Declaration of Conformity for PageWriter TC35 Cardiograph

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	PageWriter TC35 Cardiograph
Product Type	Electrocardiograph
Intended Purpose	The device is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze and store these ECG signals for review by the user.
Product Part Number(s) and Descriptions	860437, PageWriter TC35 Cardiograph
Product Options/Accessories Part Number(s) and Descriptions	This declaration also includes the following product options and accessories: n/a Available accessories are covered in separate Declarations of Conformity.
Basic UDI-DI	0884838BM766TT
Control Indicator	Software revision 1.x (or higher)
Global Medical Device Nomenclature Code (GMDN) and Description or CND or EMDN Code and Description	GMDN: 16231, Electrocardiograph, professional, multichannel CND/EMDN: Z12050301, GENERAL PURPOSE ELECTROCARDIOGRAPHS

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

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)**
Device Risk Classification	Class IIa based on Annex VIII, Rule 10, 3st Indent
Conformity Assessment Path	Annex IX excluding section (5) and (6)
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany Identification No.0123
Certificate(s) issued	The Manufacturer is certified by TÜV SÜD to the following: EU Quality Management System Certificate (MDR) as evidenced by certificate number G10 052098 0012.
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. All applied standards are part of the Technical Documentation. This following list is not exhausting see attachment A

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EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)
Common Specifications	The products listed on this Declaration of Conformity considered the set of technical and clinical requirements of the common specifications to demonstrate compliance with the legal obligations applicable to the device. n/a, as of the creation date of the Declaration of Conformity there is no Common Specification applicable.

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) and Commission Delegated Directive EU 2015/863
Device Classification	Category 8, medical device, according to Annex I RoHS classification
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 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (RED)
Device Classification	Class 1
Conformity Assessment Path	Annex II
Notified Body Name, Address, ID and EU Certificate Number	Not applicable. As the Conformity Assessment Path of this device used Module A (Internal Production Control).
Standards	The radio equipment was tested to the following standards or technical specifications: Refer to Attachment A

2 Additional information:

Manufacturer	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard Strasse 2 71034 Böblingen GERMANY SRN: DE-MF-000006026
EU Authorized Representative	n/a Philips Medizin Systeme Böblingen GmbH is located in the European Union.
Quality Certificates Issued	The Manufacturer is certified by TÜV SÜD to the following: EN ISO 13485: 2016, as evidenced by certificate number Q5 052098 0009

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

Printed Name: Kavita Mayekar-Doornenbal

Title: Regulatory Affairs Manager

Date of Issue:

12-Oct-2023

Place of Issue: Böblingen

A-860437-DoC Rev. B

Date of Expiration: 05-Oct-2025

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Attachment A

Standards and/or Common Specifications

Quality System	
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Risk Management Standards	
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
General Safety Standard	
IEC 60601-1: 2005+A1: 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
IEC 60601-1-2: 2014	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	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
Particular Safety Standards	
IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 62304: 2006+A1: 2015	Medical device software - Software life-cycle processes
Usability Standards	
IEC 62366-1: 2015	Medical devices -Part 1: Application of usability engineering to medical devices
Labeling Standards	
ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
Radio Equipment Directive (RED)	
EN 300 328 V2.2.2 (2019-07)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
EN 301 893 V2.1.1 (2017-05)	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.2.3 (2019-11)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
EN 301 489-17 V3.2.4 (2020-09)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
EN 300 440 V2.1.1 (2017-03)	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN IEC 62311:2020	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
RoHS	
IEC 63000: 2016	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Document Properties

Property	Value
Template Used/Rev.	A-Q2920-01308-T1 Rev. E
Document Class	see system managing this document
Tier	see system managing this document
Element	see system managing this document