EU Declaration of Conformity

PHILIPS

Revision: H **Number**: A-860392-90029

Based on Template/Revision: A-Q2920-01308-T1/C Record

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 TC10 Cardiograph PageWriter TC20 Cardiograph PageWriter TC30 Cardiograph PageWriter TC50 Cardiograph PageWriter TC70 Cardiograph
Product Type	Electrocardiograph
Intended Purpose	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. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.
Product Part Number(s) and Descriptions	The following product is supported by EPSEM (A-860392-90020) 860392: PageWriter TC10 Cardiograph The following products are support by EPSEM (A-860315-90021) 860332: PageWriter TC20 Cardiograph 860306: PageWriter TC30 Cardiograph 860310: PageWriter TC50 Cardiograph 860315: PageWriter TC70 Cardiograph

Product Options/Accessories Part Number(s) and Descriptions	This declaration also includes the following product options and accessories: Part Number / Description 453564659331 / PW Exchange PIM III 12L IEC 453564659351 / PW Exchange PIM III 16L IEC 860309 / Trolley for PageWriter TC30/TC50/20 860318 / Trolley for PageWriter TC70 860333 / PageWriter TC20 Cardiograph Upgrade Kit 860307 / PageWriter TC30 Upgrades 860311 / PageWriter TC50 Upgrades 860316 / PageWriter TC70 Upgrades *Note: For compatible accessories' Declaration of Conformity, please refer to the latest version provided on Philips InCenter website with document number as: A-453564918071, A-453564918111, A-453564918121, A-M5000-90323*
Basic UDI-DI	Not Applicable at this time
Control Indicator	Software revision A.01.07 (or higher) for PageWriter TC10 Cardiograph Software revision A.07 (or higher) for PageWriter TC20, TC30, TC50, TC70 Cardiographs
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	16231 Electrocardiograph, professional, multichannel

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

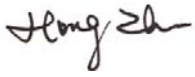
EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)**
Device Risk Classification	Class IIa based on Annex IX and Rule 10

Conformity Assessment Path	Annex II excluding (4)
Notified Body Name, Address, and ID	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany Identification 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.

2. Additional information:

Manufacturer	Philips Medical Systems 3000 Minuteman Road, Andover, MA 01810-1099, USA
EU Authorized Representative	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY
Quality Certificates Issued	The Manufacturer is certified by *TÜV SÜD* to the following: Directive 93/42/EEC on Medical Device (MDD), Annex II excluding (4), as evidenced by certificate number <G1 044649 0046 Rev 00 > EN ISO 13485:2016, as evidenced by certificate number Q5 044649 0045 Rev.00

Signature (signed for and on behalf of Philips Medical Systems):



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Date of Expiration: 26-May-2024

3. Attachment A

Standards and/or Common Specifications

Only the applicable clauses of the standard that apply to the device in scope of this DoC are covered.

Quality System	
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
General Safety Standard	
EN 60601-1: 2006 /A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-2: 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
Particular Safety Standards	
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
Others Standards	
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041: 2008+A1:2013	Information supplied by the manufacturer of medical devices