EU Declaration of Conformity

PHILIPS

Revision: L **Number**: A-860426-90006

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:

<table>
<tr><td>Product Name</td><td>IntelliSpace ECG Management System</td></tr>
<tr><td>Product Type</td><td>Clinical data collection/ management information system application software</td></tr>
<tr><td>Intended Purpose</td><td>Intended Use: The IntelliSpace ECG management system is a computer program which allows viewing, manual editing, analysis, printing and archiving of digitized ECG records.</td></tr>
<tr><td>Product Part Number(s) and Descriptions</td><td>860426 IntelliSpace ECG/ECG Management System</td></tr>
<tr><td>Product Options/Accessories Part Number(s) and Descriptions</td><td>This declaration also includes the following product options and accessories:
<table>
<tr><th>Model No.</th><th>Product Name/Description</th></tr>
<tr><td>Option B01-B05</td><td>IntelliBridge Enterprise CV interface</td></tr>
<tr><td>Option B10</td><td>Orders Worklist Application</td></tr>
<tr><td>Option B11</td><td>ADT Application</td></tr>
<tr><td>Option C30</td><td>Web API</td></tr>
<tr><td>Option C61</td><td>Non-Philips Stress PDF import</td></tr>
<tr><td>Option C70</td><td>Other PDF import</td></tr>
<tr><td>Option C71</td><td>Non-Philips ECG Acquisition</td></tr>
</table></td></tr>
<tr><td>Basic UDI-DI</td><td>Not Applicable</td></tr>
<tr><td>Control Indicator</td><td>Software Version B.02 or higher</td></tr>
<tr><td>Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description</td><td>GMDN
57967 Medical equipment clinical data interfacing software</td></tr>
</table>

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	Identification Number: 0123 TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany
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 in Attachment A. Refer to Attachment A.

2. Additional information:

Manufacturer	Philips Medical Systems 3000 Minuteman Road Andover, MA 10810-1099, 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 Product Service GmbH to the following: Directive 93/42/EEC, Annex II excluding (4). Certification number is G1 044649 0046 Rev.00

	The Manufacturer is certified by TÜV SÜD Product Service GmbH to the following: EN ISO 13485, as evidenced by certificate number Q5 044649 0048 Rev.00.
Other:	This devices was tested in the standard configurations as described in the Instructions for Use

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

Printed Name: Claire Arakaki

Title: Regulatory Affairs Manager

Date of Issue:

09-DEC-2021

Place of Issue: Andover, MA, USA

A-860426-90006 Rev L
Date of Expiration: 26-May-2024

3. Attachment A

Standards and/or Common Specifications

Quality System	
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
General Safety Standard	
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 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 62304:2006+A1:2015	Medical device software – Software life cycle processes
Particular Safety Standards	
EN 60601-2-25: 2015	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
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)
IEC 82304-1:2016	Health software – Part 1: General requirements for product safety