EU Declaration of Conformity

PHILIPS

Revision: B **Number:** B3-P35427-DoC

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	IntelliVue EEG Trunk Cables and Lead Sets
Product Type	Patient Monitor Systems
Intended Purpose	These products are for use with Philips M1027A/B EEG plug-in module. If the 4-channel trunk cable (989803180541) is used with a two-channel module (M1027A) the electrodes must be connected to channels EEG1and EEG2. For warnings, cautions, intended use, operating instructions and specifications, see your IntelliVue patient monitor's Instructions for Use.
Product Part Number(s) and Descriptions	M1931A – EEG Lead Set Adult 5 Elec. M1932A – EEG Lead Set Pedi 5 Elec. M1934A – EEG Lead Set Miniclip 5 Elec. 989803180521 – EEG Lead Set Neo/Pedi 9 Elec. 989803180531 – EEG Lead Set Miniclip 9 Elec. 989803180561 – EEG Lead Set Adult 9 Elec. M2268A – EEG Trunk Cable 2-Channel 989803180541 – EEG Trunk Cable 4-Channel
Product Options/Accessories Part Number(s) and Descriptions	This declaration also includes the following product options and accessories: n/a EEG Trunk Cables and Lead Sets are considered as accessory to the main system, thus there are no accessories for this accessory device.
Basic UDI-DI	EEG Trunk Cables: 0884838BM561T7 EEG Lead Sets: 0884838BM559TL
Control Indicator	• First MDR production:

	<table><tr><th>Part Number</th><th>LOT Number</th><th>Manufacturing Date</th></tr><tr><td>M1931A</td><td>1A</td><td>2021-03-01</td></tr><tr><td>M1932A</td><td>1A</td><td>2021-03-01</td></tr><tr><td>M1934A</td><td>1A</td><td>2021-03-01</td></tr><tr><td>989803180521</td><td>1A</td><td>2021-03-01</td></tr><tr><td>989803180531</td><td>1A</td><td>2021-03-01</td></tr><tr><td>989803180561</td><td>1A</td><td>2021-03-01</td></tr><tr><td>M2268A</td><td>1A</td><td>2021-03-01</td></tr><tr><td>989803180541</td><td>1A</td><td>2021-03-01</td></tr></table>
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	GMDN code and term: 47487 – Medical device electrical cable, reusable (EEG Trunk Cables) 35749 – electroencephalographic lead (EEG Leadsets) CND code and term: Z12030202 - Multi-Parameter Patient Monitors

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 I based on Annex VIII and Rule 1
Conformity Assessment Path	n/a No Conformity Assessment by a Notified Body is required for placing Class I Medical Devices on the EU market
Notified Body Name, Address, and ID	n/a

	Class I Medical Devices are under sole responsibility of Philips Medizin Systeme Böblingen GmbH
Certificate(s) issued	n/a Class I Medical Devices are under sole responsibility of Philips Medizin Systeme Böblingen GmbH
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: EN ISO 13485:2016 EN ISO 14971:2012 IEC 62366-1:2015 + COR1:2016 / EN 62366-1:2015 + AC:2015 IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012 / EN 60601-1:2006 + Cor.:2010 + A1:2013 IEC 60601-1-2:2014 / EN 60601-1-2:2015
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
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

2. Additional information:

Manufacturer	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard-Str. 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 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):

Date of Issue: 14-July-2021

Printed Name:
Hauke Schik

Place of Issue:
71034 Böblingen, Germany

Title:
Director Quality & Regulatory Affairs

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Date of Expiration: 26-May-2024