ECG D-SUB2
EU MDR Declaration of Conformity
Rev. 01

SCHILLER
The Art of Diagnostics

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland
SRN: CH-MF-000012722

EU Authorised Representative: SCHILLER Medizintechnik GmbH
Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany
SRN: DE-AR-000006934

QMS: Q5 041505 0115 (EN ISO 13485:2021)

Device Information				
Trade Name	ECG D-SUB2			
Product Type	General non-active non-implantable devices used in health care and other nonactive non-implantable devices (MDN: 1214).			
Intended Purpose	The ECG Cable is a multi-wire cable intended to be used to acquire the ECG signals from body surface electrodes and transmit them through wires to the compatible SCHILLER ECG devices.			
Risk Class acc. to Annex VIII MDR	I			
GMDN Code	35562			
EMDN Code	Z12050380			
Basic UDI-DI	761336500000000204Y			
Conformity Assessment acc. to MDR	Annex II and III			
REF Number	REF #	GTIN	Device Name	Date added
	2.400184	07613365003925	ECG D-SUB2 C 4.6/4.25 x10 IEC	2023-10-12
	2.400185	07613365003932	ECG D-SUB2 C 4.6/4.25 x10 AHA	2023-10-12
	2.400186	07613365003949	ECG D-SUB2 B 3.1/2.55 x10 IEC	2023-10-12
	2.400187	07613365003956	ECG D-SUB2 B 3.1/2.55 x10 AHA	2023-10-12
Standards Applied and Common Specifications	ISO 13485:2016 (EN ISO 13485:2021) ISO 14971:2019 (EN ISO 14971:2021 IEC 60601-1:2020 (EN 60601-1:2015 + A1:2021) IEC 60601-1-2:2020 (EN 60601-1-2:2015 + A1:2021) IEC 60601-1-6:2020 (EN 60601-1-6:2010 + A1:2015 + A2:2021) IEC 60601-2-25:2011 (EN 60601-2-25:2015) IEC 62366-1:2020 (EN 62366-1:2015 + AC:2015 + A1:2020) ISO 10993-1:2018 (EN ISO 10993-1:2020) IEC 82079-1:2019 ISO 20417: 2021 (EN ISO 20417:2021) ISO 15223-1:2021 (EN ISO 15223-1:2021) ISO 17664-2:2021			

We, the undersigned, declare that the medical device described above is in conformity with the applicable provision of the *MDR (EU) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council*

of 5 April 2017 on medical devices, amending *Directive 2001/83/EC, Regulation (EC) No 178/2002* and *Regulation (EC) No 1223/2009* and repealing *Council Directives 90/385/EEC and 93/42/EEC*

The products are CE marked without notified body number.

CE

RoHS 2 and 3

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment"* and its *amended Directive 2015/863/EU.*

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **SCHILLER AG**

Date of Issue: 2023-10-12
Place of Issue: Baar, Switzerland

Name: STEFAN BIGLER

Title / Function: HEAD OF RA

Signature

Name: ECKARD GLASER

Title / Function: HEAD OF QM

Signature

SCHILLER AG
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Appendix 01 List of compatible medical devices and accessories covered by this declaration

N/A, this declaration does not cover compatible medical devices and accessories.

SCHILLER AG REF No.	Device name	REF No. as per Label	Legal Manufacturer	Risk Class acc. to Annex VIII MDR /or Annex IX MDD	GMDN Code	Basic UDI-DI
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Appendix 02 List of compatible non-medical device(s), spare parts, and components covered by this declaration

N/A, this declaration does not cover non-medical devices, spare parts, and components.

SCHILLER AG REF No.	Description / Device name
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Change History

Description of Change	Revision
First version	01