DARWIN2
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

EC-certificate: G10 041505 0132

Notified Body: TÜV SÜD Product Service GmbH, ID 0123

Device Information				
Trade Name	medilog DARWIN2			
Product Type	(Diagnostic) Software (0315)			
Intended Purpose	medilog DARWIN2 is a data management and analysis program for electronic storage, transfer, display and processing of physiological signals and medical patient information combined with long-term continuous ECG or ambulatory blood pressure monitoring devices. The medilog DARWIN2 software functions include: • Displaying and analyzing of physiological signals (ECG, heart rate, ECG-derived respiration, SpO2, BP measurement, BP pulse wave analysis). • Calculating and displaying the statistical values of those data. • Detecting and classifying heart activities (atrial, ventricular) and arrhythmias. • Configuring long-term continuous ECG Holter devices and automated non-invasive sphygmomanometer blood pressure devices.			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	41651			
EMDN Code	Z12050401			
UMDNS Code	12387			
Basic UDI-DI	761336500000001455			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name	Date added
	0.282000	07613365001938	medilog DARWIN2	2024-01-18
	5.000005	07613365003673	medilog DARWIN2 AAM	2024-01-18
Software Version	2.xx.x			
Standards Applied and Common Specifications	ISO 13485:2016 (EN ISO 13485:2016/A11:2021) ISO 14971:2019 (EN ISO 14971:2019/A11:2021) IEC 62304:2015 (EN 62304:2006/A1:2015) IEC 82304-1:2016 (EN 82304-1:2017) IEC 62366-1:2020 (EN 62366-1:2015/A1:2020) IEC 60601-2-47:2012 (EN 60601-2-47:2015) ISO 20417:2021 (EN ISO 20417:2021) ISO 15223-1:2021 (EN ISO 15223-1:2021)			

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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 with notified body number.

CE 0123

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: 2024-01-18
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER	Name: STEFAN BIGLER
Title / Function: HEAD OF QUALITY MANAGEMEN	Title / Function: HEAD OF REGULATORY AFFAIRS
Signature	Signature

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

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

SCHILLER AG REF No.	Device name	REF No. as per Label	Legal Manufacturer
N/A	N/A	N/A	N/A

Appendix 02 List of compatible non-medical device(s), spare parts, and components covered by this declaration

SCHILLER AG REF No.	Description / Device name
N/A	N/A

Change History

Description of Change	Revision
First version	01