medilogAR
EU MDD Declaration of Conformity
Rev. 07

SCHILLER
The Art of Diagnostics

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

Manufacturing Site(s): SVI Austria GmbH
Frauentaler Str. 100, 8530 Deutschlandsberg, Austria

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

EC-certificate: G1 041505 0120

Notified Body: TÜV SÜD Product Service GmbH, ID 0123

Device Relevant Information			
Trade Name	medilogAR		
Product Type	Digital Holter Recorder		
Intended Purpose	The medilogAR is used to record a 3-channel ECG. The recorder is designed for a measuring duration of more than 24 hours and is therefore worn by the patient throughout the day. The preparation for the recording (attaching electrodes, etc.) is performed by the technician or doctor.		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	35162		
REF Number	REF #	GTIN	Description
	3.920740	07613365002096	medilogAR
	1A.306000	07613365002102	medilogAR Kit
Standards Applied	EN ISO 13485:2016 (ISO 13485:2016) EN ISO 14971:2012 (ISO 14971:2019) EN 60601-1:2013 (IEC 60601-1:2012) EN 60601-1-2:2015 (IEC 60601-1-2:2020) EN 60601-2-47:2001 (IEC 60601-2-47:2012) EN 60601-1-11:2010 (IEC 60601-1-11:2015) EN 60601-1-6:2010 (IEC 60601-1-6:2020) EN 62366-1:2008 (IEC 62366-1:2020) EN 62304:2006 + Cor.:2008 (IEC 62304:2015) EN ISO 10993-1:2009/AC 2010 (ISO 10993-1:2018) EN ISO 10993-5:2009 (ISO 10993-5:2009) EN ISO 10993-10:2013 (ISO 10993-10:2010) EN ISO 20417:2021 (ISO 20417:2021) EN ISO 15223-1:2016 (ISO 15223-1:2021)		

We, the undersigned, declare that the medical device described above is in conformity with the essential requirements of *93/42/EEC (MDD) Annex 2 excluding Cl. 4.* Please refer to Appendix 01 for accessories and Appendix 02 for non-MD Spare parts/components.

The device listed above is in conformity with applicable provisions of the Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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The device that is covered by the present declaration is in conformity with *DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.*

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. The products are CE marked with notified body number.

CE 0123

This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 2023-03-20
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY MANAGEMENT

Signature

Name: STEFAN BIGLER

Title / Function: HEAD OF REGULATORY AFFAIRS

Signature

Appendix 01 Accessories/devices compatible to the device covered by this declaration:

SCHILLER AG REF No.	Accessory/Device name	REF No. as per Label	Legal Manufacturer
2.400176	5-wire patient cable push-button 82 cm, medilogAR	See SCHILLER AG REF No.	SCHILLER AG
2.400177	7-wire patient cable push-button 82 cm, medilogAR	See SCHILLER AG REF No.	SCHILLER AG

Appendix 02 Non-MD Spare parts/components compatible to the device covered by this declaration:

SCHILLER AG REF No.	Accessory/Device name	REF No. as per Label
2.100850	Alcaline battery LR03, type AAA, 1.5 V	See SCHILLER AG REF No.
2.610063	Protective case (for unit protection and patient attachment)	See SCHILLER AG REF No.
2.610064	Battery compartment cover	See SCHILLER AG REF No.
2.610065	Transparent front cover	See SCHILLER AG REF No.
2.610066	Micro USB cable	46800
2.610067	Mikro SD card with adapter	KS2GRT-803M-40
2.156096	medilogAR Neck Belt	See SCHILLER AG REF No.
2.310426	USB Cable 2.0 High speed inkl. mag Adapt, 1.0m	See SCHILLER AG REF No.
2.310427	USB Cable 2.0 High speed inkl. mag Adapt, 0.3m	See SCHILLER AG REF No.

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First introduce to CE-mark region	01	15.02.2019
Update to MC TMPL	02	See MC Release Date
Update Manufacturing Site	03	See MC Release Date
Update to TMPL-0085 Rev.06 Changed SAG to SCHILLER AG Changed legal manufacturer of - 2.400176 from NICOLAY to SCHILLER AG - 2.400177 from NICOLAY to SCHILLER AG Added harmonized standards	04	2021-07-21
Removed third party accessories and only kept SCHILLER AG accessories (and spare parts/components) Split Appendix in 2 sections	05	2022-02-02
Removed third party accessories and only kept SCHILLER AG accessories (and spare parts/components) Split Appendix in 2 sections	06	2022-02-03
Updated Standards applied with current versions Removed RED Standard Updated Appendix 02 Updated DoC according TMPL SAG Word form	07	2023-03-20