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	A 3-channel ECG 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 a technician or doctor.		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	35162		
REF Number	REF #	GTIN	Description
	3.920740 (part of 1A.306000)	07613365002096	medilogAR (main device)
Standards Applied	EN 60601-1:2006 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) EN 60601-2-47:2016 (IEC 60601-2-47: 2012) EN 60601-1-11:2015 (IEC 60601-1-11: 2015) EN 60601-1-6:2010 (IEC 60601-1-6: 2013) EN 62366-1:2015 (IEC 62366-1 : 2015) EN 62304:2006/AC:2008 (IEC 62304 : 2006) ETSI EN 300 328 EN ISO 10993-1: 2009 EN ISO 10993-5: 2009 EN ISO 10993-10: 2013 EN ISO 14971: 2012 EN ISO 13485: 2016		

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.

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.

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: 21 July 2021
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY MANAGEMENT

Signature

Name: VALENTINA SHCHERBA

Title / Function: HEAD OF REGULATORY AFFAIRS

Signature

Appendix 01 Accessories/devices compatible to the device(s) 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
2.155054	Blue Sensor disposable Holter ECG electrodes	VL-00-S/25	AMBU A/S
2.100612	SpO2 sensor, medilogAR	MD300W314	CHOICEMED
2.100850	Alcaline battery LR03, type AAA, 1.5 V	See SCHILLER AG REF No.	SCHILLER AG
2.610066	Micro USB cable	46800	GOOBAY
2.610067	Mikro SD card with adapter	KS2GRT-803M-40	GOOBAY

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 (if available)	04	2021-07-21