Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

Manufacturing Site(s): SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

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	CARDIOVIT FT-1		
Product Type	Electrocardiograph		
Intended Purpose	The CARDIOVIT FT-1 is a 12-channel ECG device intended to be used by qualified personal in healthcare facilities for cardiopulmonary diagnosis in patients of all genders and ethics. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. Patent health information data is exchanged between the FT-1 and a data management system by WLAN or WiFi transmissions.		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	16231		
REF Number	REF #	GTIN	Description
	3.900860	07613365000184	CARDIOVIT FT-1 (base device HW1)
	3.900863 (part of 0A.106000)	07613365002867	CARDIOVIT FT-1 (base device 2018)
	3.900864 (part of 1A.106300)	07613365002003	CARDIOVIT FT-1 (base device CRO HW1)
	3.900865 (part of 1A.106400)	07613365003642	CARDIOVIT FT-1 (base device CRO 2018)
	3.900870 (part of 0A.106500)	07613365003284	CARDIOVIT FT-1 (base device CardioPad-2 SECA, complies FT-1)
Standards Applied	EN 60601-1:2006 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) EN 60601-2-25:1995 (IEC 60601-2-25: 2011) EN 62304:2006 (IEC 62304: 2006 + A1: 2015) IEC 62366-1: 2015 EN 60601-1-6:2010 (IEC 60601-1-6: 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
2.000041	Elektrodenset SAG Metall	See SCHILLER AG REF No.	Spes Medica s.r.l.
2.155025	Blue Sensor EKG Elektrode	R-00-S/25	AMBU A/S
2.155031	Biotabs Ag/AgC (500Stk)	See SCHILLER AG REF No.	AMBU A/S
2.155032	Adapter SNAP-CLIP/Beutel à 10	0334M	AMBU A/S
2.155034	White Sensor EKG Tabs, Bx à500	0415M	AMBU A/S
2.155035	Adapter Multi-Clip 10er Beutel/bag	2952/10	Curbell Medical Products. Inc.
2.157055	Registrierpapier FT-1 Box à 10/thermal chart paper	See SCHILLER AG REF No.	SCHILLER AG
2.200126	Netzteil 15V/2A AC-Erde/power supply ground	FSP030-RDAM	FSP / TRUMPower
2.300003	3P 2.5m Netzkabel CH,1x abgew. /power supply angled	QP022+QP018 H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300004	3P 2.5m Netzkabel UK, 2x abgew/power supply angled	QP026(10A)+QP018 H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300005	3P 2.5m Netzkabel D, 2x abgew. /power supply angled	QP004 +QP018H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300012	3P 2.5m Netzkabel HG USA,gerad/power supply angled	QP049HG+QC-01SJT3AWG18GR2500	Queen Puo Electric Co. LTD
2.300014	3P 2.5m Netzkabel CN, abgew/power supply angled	QP012+QP018 H05VV-F3G1.025M RAL7035	Queen Puo Electric Co. LTD
2.300016	3P 2.5m Netzkab. Japan 1xabge/power supply angled	QP005+QP007VCTF3G0.75GR2500	Queen Puo Electric Co. LTD
2.300025	3P Netzkabel Brasilien,1x abge/power supply angled	QP084+QP018H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.400226	10pol Pat.Kabel IEC Dknopf FT1/patient cable	See SCHILLER AG REF No.	SCHILLER AG
2.400227	10pol Pat.Kabel AHA Dknopf FT1/patient cable	See SCHILLER AG REF No.	SCHILLER AG
2.400330	10pol Pat.Kabel B`st IEC FT-1/patient cable	See SCHILLER AG REF No.	SCHILLER AG
2.400331	10pol Pat.Kabel B`st AHA FT-1/patient cable	See SCHILLER AG REF No.	SCHILLER AG

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First version on MC based on old TMPL. Signed 16.03.2016	01	Ref. MC Release Date
• New signatory person • Accessories list added Standards with year indication added	02	Ref. MC Release Date
• Retrospective inclusion of revision history • Adaption to TMPL-0085 04 • CRO version HW1, SECA versions added Updated accessories list	03	Ref. MC Release Date
• Inclusion of CRO 2018 Comment: 11.09.2015 initial CE-marking of HW1	04	Ref MC Release Date
Update to TMPL-0085 Rev.06 Changed legal manufacturer of accessories REF No: - 2.400226 JT tech Electronics to SCHILLER AG - 2.400227 JT tech Electronics to SCHILLER AG - 2.400330 JT tech Electronics to SCHILLER AG - 2.400331 JT tech Electronics to SCHILLER AG Added harmonized standards	05	2021-07-21