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		
EMDN Code	Z12050301		
UMDNS Code	11411		
REF Number	REF #	GTIN	Description
	3.900860	07613365000184	CARDIOVIT FT-1 (HW1)
	3.900863 (part of 0A.106000)	07613365002867	CARDIOVIT FT-1 (2018)
	3.900864 (part of 1A.106300)	07613365002003	CARDIOVIT FT-1 CRO (CRO HW1)
	3.900865 (part of 1A.106400)	07613365003642	CARDIOVIT FT-1 CRO (CRO 2018)
	3.900870 (part of 0A.106500)	07613365003284	CardioPad-2 (SECA, base device FT-1 2018)
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: 27 June 2022
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
2.310317	10-wire adapter cable FT-1 to D-SUB, 0.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400175	10-wire patient cable IEC, clip-type, 4.6/4.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400178	10-wire patient cable AHA, clip-type, 4.6/4.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400179	10-wire patient cable AHA, banana plug, 3.1/2.55 m	see SCHILLER AG REF No.	SCHILLER AG
2.400180	10-wire patient cable IEC, banana plug, 3.1/2.55 m	see SCHILLER AG REF No.	SCHILLER AG
2.400226	10-wire patient cable IEC, push-button, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400227	10-wire patient cable AHA, push-button, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400330	10-wire patient cable IEC, banana plug, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400331	10-wire patient cable AHA, banana plug, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG

Appendix 02 Components and Spare Parts compatible to the device(s) covered by this declaration:

SCHILLER AG REF No.	Component / Spare Part	REF No. as per Label
2.300000	Mains cable Switzerland	see SCHILLER AG REF No.
2.300002	Mains cable Schuko Europe	see SCHILLER AG REF No.
2.300003	Mains cable Switzerland, angled	see SCHILLER AG REF No.
2.300004	Mains cable UK, angled	see SCHILLER AG REF No.
2.300005	Mains cable Europe, angled	see SCHILLER AG REF No.
2.300011	Mains cable UK	see SCHILLER AG REF No.
2.300012	Mains cable (medical grade) USA	see SCHILLER AG REF No.
2.300014	Mains cable China	see SCHILLER AG REF No.
2.300016	Mains cable Japan	see SCHILLER AG REF No.
2.300024	Mains cable (medical grade) USA, angled	see SCHILLER AG REF No.
2.300025	Mains cable Brazil	see SCHILLER AG REF No.
2.200136	Power Supply 15V / 30W	see SCHILLER AG REF No.
2.310320	Earth cable for the potential equalisation stud	see SCHILLER AG REF No.
2.000147	Laser Barcode Scanner Set incl. short instructions	see SCHILLER AG REF No.
4.410300	Antriebswalze für PT1043P FT-1	see SCHILLER AG REF No.

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
• EMDN and UMDNs Code added • Appendix 01 split into 01 and 02, 02 new for components and spare parts • Accessories list adapted according to FT-1 Critical Components and Accessories: ▪ accessories added: 2.400175, 2.400178, 2.400179, 2.400180 and 2.310317 to Appendix 01 and 2.300000, 2.300002, 2.300011 and 2.300024 to Appendix 02 ▪ changed: 2.200136 instead of 2.200126, ▪ removed (medical devices and non Schiller legal manufacturer): 2.000041, 2.155025, 2.155031, 2.155032, 2.155034, 2.155035, 2.157055 (new Legal manufacturer Diagramma)	06	2022-06-27