	Declaration of Conformity		SCHILLER The Art of Diagnostics
	CH-DHF-0623 Rev. 04	Effective Date : 22 Mar 2021	

EU MDD Declaration of Conformity

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

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


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	<p>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.</p> <p>Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.</p> <p>Patent health information data is exchanged between the FT-1 and a data management system by WLAN or WiFi transmissions.</p>
Risk Class acc. to Annex II MDD	Ila
GMDN Code	16231
REF Number(s) and description	3.900860 base device FT-1 HW1 3.900863 base device FT-1 2018 (part of 0A.106000 FT-1 complete) 3.900864 base device FT-1 CRO HW1 (part of 1A.106300 CARDIOVIT FT-1 CRO complete) 3.900865 base device FT-1 CRO 2018 (part of 1A.106400 CARDIOVIT FT-1 CRO 2018 complete) 3.900870 base device CardioPad-2 SECA (part of 0A.106500 CardioPad-2 complete)
Standards Applied	IEC 60601-1: 2012 IEC 60601-1-2: 2014 IEC 60601-2-25: 2011 IEC 62304: 2006 + A1: 2015 IEC 62366-1: 2015 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 that is covered by the present declaration is in conformity with Dir. 2011/65/EU (Art. 4) of the European Parliament and of the Council of 8 June 2011 on the restriction of use of certain hazardous substances (RoHS).

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This declaration of conformity is issued under the sole responsibility of SCHILLER AG.

This declaration is valid until 16 April 2024 and supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 29.03.2021

Place of Issue: Baar, Switzerland



Eckard Glaser
Head of Quality Management



Valentina Shcherba
Head of Regulatory Affairs



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Appendix 01 Accessories/devices Compatible to the Device Covered by This Declaration

SCHILLER AG REF Number	Accessory/Device Name	Legal Manufacturer
2.000041	Elektrodenstet SAG Metall	Spes Medica s.r.l.
2.155025	Blue Sensor EKG Elektrode	AMBU A/S
2.155031	Biotabs Ag/AgC (500Stk)	AMBU A/S
2.155032	Adapter SNAP-CLIP/Beutel à 10	AMBU A/S
2.155034	White Sensor EKG Tabs, Bx à500	AMBU A/S
2.155035	Adapter Multi-Clip 10er Beutel/bag	Curbell Medical Products. Inc.
2.157055	Registrierpapier FT-1 Box à 10/thermal chart paper	SCHILLER AG
2.200126	Netzteil 15V/2A AC-Erde/power supply ground	FSP / TRUMPower
2.300003	3P 2.5m Netzkabel CH, 1x abgew. /power supply angled	Queen Puo Electric Co. LTD
2.300004	3P 2.5m Netzkabel UK, 2x abgew./power supply angled	Queen Puo Electric Co. LTD
2.300005	3P 2.5m Netzkabel D, 2x abgew. /power supply angled	Queen Puo Electric Co. LTD
2.300012	3P 2.5m Netzkabel HG USA,gerad/power supply angled	Queen Puo Electric Co. LTD
2.300014	3P 2.5m Netzkabel CN, abgew/power supply angled	Queen Puo Electric Co. LTD
2.300016	3P 2.5m Netzkab. Japan 1xabge/power supply angled	Queen Puo Electric Co. LTD
2.300025	3P Netzkabel Brasilien, 1x abge/power supply angled	Queen Puo Electric Co. LTD
2.400226	10pol Pat.Kabel IEC Dknopf FT1/patient cable	JT tech Electronics
2.400227	10pol Pat.Kabel AHA Dknopf FT1/patient cable	JT tech Electronics
2.400330	10pol Pat.Kabel B'st IEC FT-1/patient cable	JT tech Electronics
2.400331	10pol Pat.Kabel B'st AHA FT-1/patient cable	JT tech Electronics

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version/ Revision	Release Date
First version on MC based on old TMPL. Signed 16.03.2016	01	Ref. MC Release Date
<ul style="list-style-type: none"> New signatory person Accessories list added Standards with year indication added 	02	Ref. MC Release Date
<ul style="list-style-type: none"> Retrospective inclusion of revision history Adaption to TMPL-0085 04 CRO version HW1, SECA versions added Updated accessories list 	03	Ref. MC Release Date
<ul style="list-style-type: none"> Inclusion of CRO 2018 Comment: 11.09.2015 initial CE-marking of HW1 	04	Ref MC Release Date