



**CARDIOVIT FT-1**  
**EU MDR Declaration of Conformity**  
**Rev. 01**

**SCHILLER**  
 The Art of Diagnostics

**Declaration of Conformity**

**Manufacturer:** SCHILLER AG  
 Altgasse 68, 6341 Baar, Switzerland  
**SRN:** CH-MF-000012722

**EU Authorised Representative:** SCHILLER Medizintechnik GmbH  
 Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany  
**SRN:** DE-AR-000006934

**QMS:** Q5 041505 0115

**EC-certificate:** G10 041505 0132

**Notified Body:** TÜV SÜD Product Service GmbH, ID 0123

Device Information				
<b>Trade Name</b>	<b>CARDIOVIT FT-1</b>			
<b>Product Type</b>	Electrocardiograph			
<b>Intended Purpose</b>	The CARDIOVIT FT-1 / CardioPad-2 is a 12 lead electrocardiograph intended to be used indoor in a clinical setting by nurses or personnel with locally equivalent education and licensing level under the direct supervision of a licensed physician to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs to support diagnosis by a licensed physician in adult and paediatric patients at rest.			
<b>Risk Class acc. to Annex VIII MDR</b>	IIa			
<b>GMDN Code</b>	16231			
<b>EMDN Code</b>	Z120503			
<b>UMDNS Code</b>	11411			
<b>Basic UDI-DI</b>	7613365000000095C			
<b>Conformity Assessment acc. to MDR</b>	Annex IX Chapters I and III			
<b>REF Number</b>	<b>REF #</b>	<b>GTIN</b>	<b>Device Name</b>	<b>Date added</b>
	3.900863 (part of 0A.106000)	07613365002867	CARDIOVIT FT-1	2024-11-25
	3.900870 (part of 0A.106500)	07613365003284	CardioPad-2	2024-11-25
	3.900865 (part of 1A.106400)	07613365003642	CARDIOVIT FT-1 (CRO)	2024-11-25
<b>Standards Applied and Common Specifications</b>	ISO 13485:2016 (EN ISO 13485 :2016+A1 :2021) ISO 14971:2019 (EN ISO 14971:2019/A11:2021) IEC 60601-1:2020 (EN 60601-1:2015 + A1:2021) IEC 60601-1-2:2020 (EN 60601-1-2:2015 + A1:2021) IEC 62304:2015 (EN 62304:2006 + Cor.:2008 + A1:2015) IEC 62366-1:2020 (EN 62366-1:2015 + AC:2015 + A1:2020)			



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Device Information	
	IEC 60601-1-6:2020 (EN 60601-1-6:2010 + A1:2015 + A2:2021)
	IEC 60601-2-25:2011 (EN 60601-2-25:2015)
	ISO 15223-1:2021 (EN ISO 15223-1:2021)

We, the undersigned, declare that the medical device described above is in conformity with the applicable provision of the *MDR (EU) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*

The products are CE marked with notified body number.



**RoHS 2 and 3**

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment"* and its amended *Directive 2015/863/EU*.

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **SCHILLER AG**

Date of Issue: 25. November 2024

Place of Issue: Baar, Switzerland

Name: STEFAN BIGLER

Name: AYNUR ASLANOVA

Title / Function: Head of Regulatory Affairs

Title / Function: Head of Quality

Signature

**SCHILLER AG**

Altgasse 68  
CH-6341 Baar/Switzerland

Signature



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**Appendix 01 List of compatible medical devices and accessories covered by this declaration**

SCHILLER AG REF No.	Accessory/Device name	Accessory/Device description	REF No. as per Label	Legal Manufacturer
2.310317	ECG FS D-SUB 0.25 AC	adapter cable FT-1/MS-12 USB to D-SUB, 0.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400175	ECG D-SUB C 4.6/4.25 x10 IEC	10-wire patient cable IEC, clip-type, 4.6/4.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400178	ECG D-SUB C 4.6/4.25 x10 AHA	10-wire patient cable AHA, clip-type, 4.6/4.25 m	see SCHILLER AG REF No.	SCHILLER AG
2.400179	ECG D-SUB B 3.1/2.55 x10 AHA	10-wire patient cable AHA, banana plug, 3.1/2.55 m	see SCHILLER AG REF No.	SCHILLER AG
2.400180	ECG D-SUB B 3.1/2.55 x10 IEC	10-wire patient cable IEC, banana plug, 3.1/2.55 m	see SCHILLER AG REF No.	SCHILLER AG
2.400226	ECG FS P 2.1/1.6 x10 IEC	10-wire patient cable IEC, push-button, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400227	ECG FS P 2.1/1.6 x10 AHA	10-wire patient cable AHA, push-button, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400330	ECG FS B 2.1/1.6 x10 IEC	10-wire patient cable IEC, banana plug, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG
2.400331	ECG FS B 2.1/1.6 x10 AHA	10-wire patient cable AHA, banana plug, 2.1/1.6 m	see SCHILLER AG REF No.	SCHILLER AG

**Appendix 02 List of compatible non-medical device(s), spare parts, and components covered by this declaration**

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



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**Change History**

Description of Change	Revision
First version	01