FT-2 EU MDR Declaration of Conformity
Rev. 01

SCHILLER
The Art of Diagnostics

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				
Trade Name	CARDIOVIT FT-2			
Product Type	Electrocardiograph			
Intended Purpose	The CARDIOVIT FT-2 is a electrocardiograph device intended to be used by or under the direct supervision of a licensed physician in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs to support diagnosis in adult and paediatric patients at rest. The spirometry option is intended to be used by or under the direct supervision of a licensed physician in healthcare facilities to record, analyze, display and print measurements and waveforms of pulmonary function tests to support diagnosis in adult and pediatric patients.			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	16231			
EMDN Code	Z120503			
Basic UDI-DI	761336500000000175B			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name	Date added
	3.900880	07613365003536	CARDIOVIT FT-2	2024-01-10
Standards Applied and Common Specifications	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) 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 26782:2009 (EN ISO 26782:2009) ISO 23747:2015 (EN ISO 23747:2015) 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.

CE 0123

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: 2024-01-10
Place of Issue: Baar, Switzerland

Name: STEFAN BIGLER	Name: ECKARD GLASER
Title / Function: Head of Regulatory Affairs	Title / Function: Head of Quality Management
Signature	Signature

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

SCHILLER AG REF No.	Device name	REF No. as per Label	Legal Manufacturer
3.900890	CARDIOVIT FT-2 / TP*	N/A	SCHILLER AG

*to be used together with FT-2. Thermal printer (TP) is not classified as a separate medical device.

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

SCHILLER AG REF No.	Description / Device name
2.310005	Potential equalisation cable, 5 m
2.300000	Mains cable Switzerland, straight, 2.5 m
2.300002	Mains cable Schuko Europe, straight, 2.5 m
2.300011	Mains cable UK, straight, 2.5 m
2.300012	Mains cable USA, medical grade, straight, 2.5 m
2.300014	Mains cable China, angled, 2.5 m
2.300016	Mains cable Japan, angled, 2.5 m
2.300025	Mains cable Brazil, angled, 2.5 m
2.200134	Medical power supply 100 — 240 VAC, max. 2.0 A—0.7 A, 50 —60 Hz output 24V, 6.25A Note: Only qualified service technicians trained by SCHILLER may re-place the power supply if built in the Trolley (as described in the service manual)
2.000147	Barcode scanner set including barcode scanner (2.200208 // LS2208-SR20001R-UR) and SCHILLER User guide "Barcode scanner for use with SCHILLER units" (2.510721)

Change History

Description of Change	Revision
First version	01