



CS-104
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 CS-104			
Product Type	(Diagnostic) Software (0315)			
Intended Purpose	<p>The CARDIOVIT CS-104 is a 12-lead ECG and spirometry system intended to be used by trained medical professionals in healthcare facilities for cardiopulmonary diagnosis in adult and pediatric patients.</p> <p>Analysis of the ECG and spirometry signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.</p> <p>The CARDIOVIT CS-104 is intended to acquire ECG signals from body surface electrodes, and record, analyze display and print ECGs for cardiological diagnosis in adult and pediatric patients.</p> <p>The Vector ECG option is intended to provide a 3-dimensional view of the electrical activity, to add value to the diagnostic of the hearts backside.</p> <p>Using the optional spirometry module and the associated accessories, the CARDIOVIT CS-104 is intended to record, analyze, display and print measures and waveforms of pulmonary function tests for the diagnosis of lung diseases in adult and pediatric patients able to understand the test instructions.</p>			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	16231 / 13680			
EMDN Code	Z12050392			
UMDNS Code	15685 / 11407			
Basic UDI-DI	76133650000000114X			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name	Date added
	5.111001	07613365003918	CARDIOVIT CS-104	2024-01-18
Standards Applied and Common Specifications	<p>ISO 13485:2016 (EN ISO 13485:2016/A11:2021)</p> <p>ISO 14971:2019 (EN ISO 14971:2019/A11:2021)</p> <p>IEC 60601-2-25:2011 (EN 60601-2-25:2015)</p> <p>IEC 62304:2015 (EN 62304:2006/A1:2015)</p> <p>IEC 62366-1:2020 (EN 62366-1:2015/A1:2020)</p> <p>IEC 60601-1-6:2020 (EN 60601-1-6:2010/A2:2021)</p> <p>ISO 20417:2021 (EN ISO 20417:2021)</p> <p>ISO 15223-1:2021 (EN ISO 15223-1:2021)</p>			



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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: 2024-01-18

Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Name: STEFAN BIGLER

Title / Function: HEAD OF QUALITY
MANAGEMENT

Title / Function: HEAD OF REGULATORY
AFFAIRS

Signature

Signature

SCHILLER AG
Altgasse 68
H-6341 Baar/Switzerland



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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
2.310317	ECG FS D-SUB 0.25 AC Adapter for suction device compatible with MS-12 USB	See SCHILLER AG REF No.	SCHILLER AG
2.310323	ECG FS D-SUB 0.25 Tapuz AC Adapter Tapuz belt for MS-12 blue (adapter cable for standard D-SUB patient cables, not suitable for suction pumps)	See SCHILLER AG REF No.	SCHILLER AG
2.400226	ECG 10-wire patient cable IEC dot clip 2.1 m 10-wire patient cable snap connection IEC	See SCHILLER AG REF No.	SCHILLER AG
2.400227	ECG 10-wire patient cable AHA dot clip 2.1 m 10-wire patient cable snap connection AHA	See SCHILLER AG REF No.	SCHILLER AG
2.400330	ECG 10-wire patient cable IEC banana plug 2.1 m 10-wire patient cable banana connection IEC	See SCHILLER AG REF No.	SCHILLER AG
2.400331	ECG 10-wire patient cable AHA banana plug 2.1 m 10-wire patient cable banana connection AHA	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 Swiss type, straight
2.300002	Mains cable Schuko Europe, straight
2.300003	Mains cable AC Swiss, 90° angled
2.300004	Mains cable UK, 90° angled
2.300005	Mains cable Schuko Europe 2,5m, 90° angled
2.300011	Mains cable UK, straight
2.300012	Mains cable USA hospital grade, 2,5m straight
2.300014	Mains cable, China, 90° angled
2.300016	Mains cable black, Japan, 90° angled
2.300024	Mains cable USA hospital grade, 2,5m, 90°angled
2.300025	Mains cable Brazil, 90° angled
4.150391	24" Monitor
4.150392	OptiPlex 7080
4.150406	OptiPlex 7000
2.101118	DRAWER FOR MULTIX TROLLEYS
2.101119	BASKET FOR MULTIX TROLLEYS



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SCHILLER AG REF No.	Description / Device name
2.101120	SHELF 45x38 CM FOR TROLLEYS X2, X3
2.101121	HOLDER BARCODE SCANNER FOR MULTIX TROLLEYS
2.101158	HOLDER FT-1 FOR TROLLEY X4
2.101159	SPIROSCOUT SPPLUS HOLDER FOR X4
2.101183	DT-80 HOLDER FOR TROLLEYS X4 AND X5
2.101186	DT-100 HOLDER FOR TROLLEYS X4 AND X5

Change History

Description of Change	Revision
First version	01