

	EU Declaration of Conformity (MDD)		SCHILLER <small>The Art of Diagnostics</small>
	CH-DHF-2893 Rev. 08	See Confluence page	

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 CS-104	
Product Type	Electrocardiograph	
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>	
Risk Class acc. to Annex IX MDD	IIa	
GMDN Code	16231	
REF Number	REF #	Description
	0A.111000	CARDIOVIT CS-104 (complete)
	0A.111010	CARDIOVIT CS-104 (system complete)
	0A.111020	CARDIOVIT CS-104 (UK version)
	0A.111030	CARDIOVIT CS-104 (update set)
	0A.111040	CARDIOVIT CS-104 (for replacement delivery)
	0A.111100	CARDIOVIT CS-104 (Spiro complete)
Standards Applied	EN ISO 13485:2016 (ISO 13485:2016) EN ISO 14971:2012 (ISO 14971:2019) EN 60601-1:2006/A1:2013 (IEC 60601-1:2020) EN 60601-1-2:2015 (IEC 60601-1-2:2014) EN 60601-2-25:1999 (IEC 60601-2-25:2011) EN 62366:2008 (IEC 62366-1:2015) EN 60601-1-6:2010 (IEC 60601-1-6:2013) EN 62304:2006/AC:2008 (IEC 62304:2015) IEC 60529:2013 EN ISO 10993-1:2009/AC:2010	

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 and Appendix 02 for non-MD Spare parts/components.

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.



EU Declaration of Conformity (MDD)

SCHILLER
The Art of Diagnostics

CH-DHF-2893 Rev. 08

See Confluence page

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.



This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 2023-04-17
Place of Issue: Baar, Switzerland

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

Name: ECKARD GLASER

Name: STEFAN BIGLER

Title / Function: HEAD OF QUALITY
MANAGEMENT

Title / Function: HEAD OF REGULATORY
AFFAIRS

Signature

Signature



EU Declaration of Conformity (MDD)

SCHILLER
The Art of Diagnostics

CH-DHF-2893 Rev. 08

See Confluence page

Appendix 01 Accessories/devices compatible to the device(s) covered by this declaration:

SCHILLER AG REF No.	Accessory/Device name (Description IfU SCHILLER AG)	REF No. as per Label	Legal Manufacturer
2.310317	15 pin adapter cable to standard ECG cable & suction pumps / Adapter for suction device compatible with MS-12 USB	See SCHILLER AG REF No.	SCHILLER AG
2.310323	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
3.920725	MS-12 USB	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.	Components / spare parts	REF No. as per Label
2.300000	Mains cable Swiss type, straight	See SCHILLER AG REF No.
2.300002	Mains cable Schuko Europe, straight	See SCHILLER AG REF No.
2.300003	Mains cable AC Swiss, 90° angled	See SCHILLER AG REF No.
2.300004	Mains cable UK, 90° angled	See SCHILLER AG REF No.
2.300005	Mains cable Schuko Europe 2,5m, 90° angled	See SCHILLER AG REF No.
2.300011	Mains cable UK, straight	See SCHILLER AG REF No.
2.300012	Mains cable USA hospital grade, 2,5m straight	See SCHILLER AG REF No.
2.300014	Mains cable, China, 90° angled	See SCHILLER AG REF No.
2.300016	Mains cable black, Japan, 90° angled	See SCHILLER AG REF No.
2.300024	Mains cable USA hospital grade, 2,5m, 90°angled	See SCHILLER AG REF No.
2.300025	Mains cable Brazil, 90° angled	See SCHILLER AG REF No.
4.150391	24" Monitor	P2422H
4.150392	OptiPlex 7080	OptiPlex 7080 MFF XE XCTO
4.150406	OptiPlex 7000	OptiPlex 7000 Micro

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
e.g. first introduced to the CE-market	01	Ref. MC Release Date
<ul style="list-style-type: none"> - Addition of the device dependent revision history - Deletion of the template revision history - Addition of all the article numbers - Addition of all biocompatibility standards - Legal manufacturer verification and correction 	02	Effective Date
Adaptation of the intended purpose		
Addition of the p/n OA.111040, "Terra PC-mini V4 / i5 / 9th ge"	03	Effective Date
Update to TMPL-0085 Rev.06	04	2021-07-21
Added harmonized standards		
Addition of the following articles: <ul style="list-style-type: none"> - 2.310323 Adapter Tapuz belt for MS-12 blue - 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 - 2.300024 Mains cable USA hospital grade, 2,5m, 90°angled 	05	2021-09-30
Split Appendix in part 01 (accessories and devices compatible) and 02 (components and spare parts)		
Remove of patient cables covered by the MS-12 Blue: <ul style="list-style-type: none"> - 2.400222 10-lead patient cable IEC snap type - 2.400223 Patient cable 10-lead Snap type AHA color code - 2.400224 10-wire patient cable AHA banana plug - 2.400225 10-wire patient cable banana plug IEC - 2.400228 10-wire patient cable clip type IEC - 2.400229 10-wire patient cable clip type AHA 	06	2021-11-10
Addition of : EN ISO 10993-5: 2009		
Addition of the following parts: <ul style="list-style-type: none"> - 4.150391 24" Monitor - 4.150392 OptiPlex 7080 	07	2021-11-19
Addition of 4.150406 OptiPlex 7000 Update version of standards applied	08	2023-04-17