

	Declaration of Conformity (MDD)		SCHILLER <small>The Art of Diagnostics</small>
	CH-DHF-2893 Rev. 02	Effective Date : 05 Nov 2019	

EU Declaration of Conformity (MDD)

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 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 paediatric 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 II MDD	Ila
GMDN Code	16231
REF Number	0A.111000 0A.111010 0A.111020 0A.111030 0A.111100
Standards Applied	IEC 60601-1:2012 IEC 60601-1-2:2014 IEC 60601-2-25:2011 IEC 62366-1:2015 IEC 60601-1-6:2013 IEC 62304:2015 IEC 60529: 2013 EN ISO 14971:2012 EN ISO 13485:2016 EN ISO 10993-1: 2009 EN ISO 10993-10: 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 Annex 2.4. 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

Place of Issue: Baar, Switzerland



Johann-Jakob Schmid
Senior Vice-President

October 30, 2019

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Appendix 01 Accessories Compatible to the Device Covered by This Declaration

Accessory Name	Legal Manufacture	REF Number
MS-12 USB	SCHILLER AG	3.920725
MS-12 bleu	SCHILLER AG	3.920720
ECG 10-wire patient cable IEC banana plug 2.1 m	SCHILLER AG	2.400330
ECG 10-wire patient cable AHA banana plug 2.1 m	SCHILLER AG	2.400331
ECG 10-wire patient cable IEC dot clip 2.1 m	SCHILLER AG	2.400226
ECG 10-wire patient cable AHA dot clip 2.1 m	SCHILLER AG	2.400227
BIOTABS ECG Electrodes	Ambu A/S	2.155031
Ambu Snap Clip Clip Connector for ECG tab electrode	Ambu A/S	2.155032
Ambu BlueSensor R ECG Electrodes	Ambu A/S	2.155025
ECG KIT	Spes Medica s.r.l.	2.000041
10-wire patient cable banana plug IEC	SCHILLER AG	2.400225
10-wire patient cable AHA banana plug	SCHILLER AG	2.400224
10-lead patient cable IEC snap type	SCHILLER AG	2.400222
Patient cable 10-lead Snap type AHA color code	SCHILLER AG	2.400223
10-wire patient cable clip type IEC	SCHILLER AG	2.400228
10-wire patient cable clip type AHA	SCHILLER AG	2.400229
Ergo Belt	SCHILLER AG	2.100060
CARDIOVIT FT-1	SCHILLER AG	3.900863
ECG Kit	Spes Medica s.r.l.	2.000052
Suction Electrode 4 mm	Spes Medica s.r.l.	2.155000
Set of 4 clamp electrodes	Spes Medica s.r.l.	2.155020