

	Declaration of Conformity MDD		SCHILLER <small>The Art of Diagnostics</small>
	CH-DHF-0527 Rev. 05	Effective Date : 12 Feb 2021	

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 AT-102 G2
Product Type	Electrocardiograph
Intended Purpose	<p>The CARDIOVIT AT-102 G2 is a 12-lead electrocardiograph device intended to be used by or under the direct supervision of a licensed healthcare practitioner in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs for diagnosis in adult and paediatric patients.</p> <p>The spirometry option is intended to record, analyze, display and print measurements and waveforms of pulmonary function tests for the diagnosis in adult and pediatric patients.</p> <p>The exercise option is intended to acquire ECG signals from body surface electrodes record, analyse, display and print ECGs of adult and paediatric patients undergoing stress exercise testing.</p>
Risk Class acc. To Annex II MDD	Ila
GMDN Code	16231
REF Number	3.912410, 3.912417 (part of 0A.108000 complete) 3.912421 (part of 0A.108100 complete)
Standards Applied	IEC 60601-1: 2012 IEC 60601-1-2: 2014 IEC 60601-2-25: 2011 IEC 62304: 2006 + A1: 2015 IEC 62366-1: 2015 IEC 60601-1-6: 2013 EN ISO 14971: 2012 EN ISO 13485: 2016

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)*.

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.



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Signed for on behalf of: Schiller AG

Place of Issue: Baar, Switzerland

Eckard Glaser
Head of Quality Management

Valentina Shcherba
Head of Regulatory Affairs



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Appendix 01 Accessories Compatible to the Device Covered by This Declaration

Accessory Name	Legal Manufacturer	REF Number
SpiroScout SP plus (Pulmonary function diagnostic device: 04 421 0020, IIa acc. to 93/42/EC)	GANSORN MEDIZIN ELECTRONIC GMBH	1.500041
ScoutTube Mouthpieces (x50) (01 942 620)	GANSORN MEDIZIN ELECTRONIC GMBH	2.101123
Disposable nose clips (x50) (A508 / MAF-TDS-261, via GANSORN MEDIZIN ELECTRONIC GMBH: 01 941 0906)	GVS	2.101187
ETM Software AT-102 G2 (ECG Treatment Module)	SCHILLER AG	5.108002
SCHILLER Culprit Coronary Artery Algorithm Software (CCAA) AT-102	SCHILLER AG	5.108004
Worklist Software AT-102 G2	SCHILLER AG	5.108005
Basic Ergometry Software AT-102 G2	SCHILLER AG	5.108006
Thermal chart paper AT-102 G2	SCHILLER AG	2.157050
10-wire patient cable IEC 2m, banana plug type	SCHILLER AG	2.400070
10-wire patient cable AHA 2m, banana plug type	SCHILLER AG	2.400071
10-wire patient cable IEC, 3.5m clip-type	SCHILLER AG	2.400095
10-wire patient cable, clip type, 3.5m, AHA	SCHILLER AG	2.400104
10-wire patient cable IEC, 3,5m clip	SCHILLER AG	2.400175
10-wire patient cable IEC, 2m with banana plug	SCHILLER AG	2.400180
10-wire patient cable AHA, 3,5m clip	SCHILLER AG	2.400178
10-wire patient cable AHA, 2m with banana plug	SCHILLER AG	2.400179
Mains cable Swiss type, straight	QUEEN PUO	2.300000
Mains cable Schuko Europe, straight	QUEEN PUO	2.300002
Mains cable UK, straight	QUEEN PUO	2.300011
Mains cable USA hospital grade, 2,5m straight	QUEEN PUO	2.300012
Mains cable, China, 90° angled	QUEEN PUO	2.300014
Mains cable black, Japan, 90° angled	QUEEN PUO	2.300016
Mains cable Brazil, 90° angled	QUEEN PUO	2.300025
Ground cable with 6mm MC plug	SCHILLER AG	2.310005
Blue Sensor Disposable ECG Electrode, ø 48mm, Set of 25 pcs	AMBU A/S	2.155025
White Sensor EKG Tabs	AMBU A/S	2.155034
Snap-Clip-Adapter AMBU Substitute 0334M with 2952/10	AMBU A/S	2.155035
SNAP-CLIP Adapter for banana-plug cables pouch of 10 pcs	AMBU A/S	2.155032
Abrasive pads RADIO-PREPS, pouch of 50 pcs	AMBU A/S	2.155030
Suction electrode 4mm	SPES MEDIC	2.155000
Replacement bulb for suction electrode 2.155000	SCHILLER AG	2.155060
Adult clamp extremity electrode, set of 4 pcs	SCHILLER AG	2.155020
Electrode gel 50 ml net 4.00	SPES MEDIC	2.158000
ECG electrode contact spray, bottle 250 ml	SCHILLER AG	2.158006
Set of adult ECG electrodes incl. 6 suction electrodes, 4 clamp extremity electrodes and 1 ECG electrode gel 50ml	SPES MEDIC	2.000041
Set of children ECG electrodes incl. 6 suction electrodes, 4 clamp extremity electrodes and 1 ECG electrode gel 50ml	SPES MEDIC	2.000052
Dust cover for AT-102 G2	SCHILLER AG	2.160017
Trolley X1 with mounting bracket	Multix Solutions s.r.l.	2.101125
Drawer for trolleys X1, X2	SCHILLER AG	2.101118
Basket translucent for trolleys X1, X2	SCHILLER AG	2.101119
Holder Barcodescanner for trolleys X1, X2	SCHILLER AG	2.101121
Holder suction pump Ergo Vaq for trolley X1	SCHILLER AG	2.101122
ECG cable support for trolley X1	SCHILLER AG	2.101130

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First introduce to CE-mark region	01	08.05.2018
Update to MC TMPL Added 10993-x	02	See MC Release Date
Update for new device variant 3. 912421 Update for additional accessories 2.400175, 2.400178, 2.400179 and 2.400180 Update standard 10993-1, correct standard 10993-10	03	See MC Release Date
The following article was end of life: <ul style="list-style-type: none"> • 2.155031: Biotabs ECG Electrodes <p>Was replaced by:</p> <ul style="list-style-type: none"> • 2.155034: White Sensor EKG Tabs <p>Added the 2.155035 as a replacement for 2.155032</p>	04	Effective Date
Addition of Spirometry to intended purpose incl. exercise ECG Removal of biocomp. standards to harmonized standards Replacement of signatory person from JJS to VASH/EGLA Addition of 1.500041, 2.101123, 2.101187 to the accessories list Changed legal manufacturer to Multix for 2.101125 Abbreviations of SAG replaced by SCHILLER AG	05	See MC Release date