

	EU Declaration of Conformity (MDD) CH-DHF-0527 Rev. 06 Effective Date : 21.07.2021		SCHILLER The Art of Diagnostics
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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 AT-102 G2		
Product Type	Electrocardiograph		
Intended Purpose	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. 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. 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.		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	16231		
REF Number	REF #	GTIN	Description
	3.912410 (part of 0A.108000)	07613365001860	CARDIOVIT AT-102 G2 (international)
	3.912417 (part of 0A.108000)	07613365003321	CARDIOVIT AT-102 G2 (Romania keyboard)
	3.912421 (part of 0A.108100)	07613365003260	CT8000P-2 SECA (equals 3.912410)
System Version	System: 1.2.0		
Standards Applied	EN 60601-1:2006/A1:2013 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) EN 60601-2-25:1995 (IEC 60601-2-25: 2011) EN 62304:2006/AC:2008 (IEC 62304: 2006 + A1: 2015) EN 62366:2008 (IEC 62366-1: 2015) EN 60601-1-6:2010 (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 Cl. 4. Please refer to Appendix 01 for accessories.

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.



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The Art of Diagnostics

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: 21 July 2021

Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY
MANAGEMENT

Signature

Name: VALENTINA SHCHERBA

Title / Function: HEAD OF REGULATORY
AFFAIRS

Signature

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

SCHILLER AG REF No.	Accessory/Device name	REF No. as per Label	Legal Manufacturer
1.500041	SpiroScout SP plus (Pulmonary function diagnostic device: 04 421 0020, IIa acc. to 93/42/EC)	04 421 0020	GANSORN MEDIZIN ELECTRONIC GMBH
2.101123	ScoutTube Mouthpieces (x50) (01 942 620)	01 942 0620	GANSORN MEDIZIN ELECTRONIC GMBH
2.101187	Disposable nose clips (x50) (A508 / MAF-TDS-261, via GANSORN MEDIZIN ELECTRONIC GMBH: 01 941 0906)	A508 / MAF-TDS-261	GVS
5.108002	ETM Software AT-102 G2 (ECG Treatment Module)	See SCHILLER AG REF No.	SCHILLER AG
5.108004	SCHILLER Culprit Coronary Artery Algorithm Software (CCAA) AT-102	See SCHILLER AG REF No.	SCHILLER AG
5.108005	Worklist Software AT-102 G2	See SCHILLER AG REF No.	SCHILLER AG
5.108006	Basic Ergometry Software AT-102 G2	See SCHILLER AG REF No.	SCHILLER AG
2.157050	Thermal chart paper AT-102 G2	See SCHILLER AG REF No.	SCHILLER AG
2.400070	10-wire patient cable IEC 2m, banana plug type	See SCHILLER AG REF No.	SCHILLER AG
2.400071	10-wire patient cable AHA 2m, banana plug type	See SCHILLER AG REF No.	SCHILLER AG
2.400095	10-wire patient cable IEC, 3.5m clip-type	See SCHILLER AG REF No.	SCHILLER AG
2.400104	10-wire patient cable, clip type, 3.5m, AHA	See SCHILLER AG REF No.	SCHILLER AG
2.400175	10-wire patient cable IEC, 3,5m clip	See SCHILLER AG REF No.	SCHILLER AG
2.400180	10-wire patient cable IEC, 2m with banana plug	See SCHILLER AG REF No.	SCHILLER AG
2.400178	10-wire patient cable AHA, 3,5m clip	See SCHILLER AG REF No.	SCHILLER AG
2.400179	10-wire patient cable AHA, 2m with banana plug	See SCHILLER AG REF No.	SCHILLER AG
2.300000	Mains cable Swiss type, straight	QP022+QP007H05VV-F3G1GR2500	QUEEN PUO
2.300002	Mains cable Schuko Europe, straight	S03 ST3 H05VV-F 3G1.00MM ² 2.5M GREY	QUEEN PUO
2.300011	Mains cable UK, straight	QP026(13A)QP007H05VV-F3G1GR2500	QUEEN PUO
2.300012	Mains cable USA hospital grade, 2,5m straight	QP049HG+QC-01SJT3AWG18GR2500	QUEEN PUO
2.300014	Mains cable, China, 90° angled	QP012+QP018 H05VV-F3G1.025M RAL7035	QUEEN PUO
2.300016	Mains cable black, Japan, 90° angled	QP005+QP007VCTF3G0.75GR2500	QUEEN PUO
2.300025	Mains cable Brazil, 90° angled	QP084+QP018H05VV-F3G1GR2500	QUEEN PUO
2.310005	Ground cable with 6mm MC plug	See SCHILLER AG REF No.	SCHILLER AG



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The Art of Diagnostics

2.155025	Blue Sensor Disposable ECG Electrode, ø 48mm, Set of 25 pcs	R-00-S/25	AMBU A/S
2.155034	White Sensor EKG Tabs	0415M	AMBU A/S
2.155035	Snap-Clip-Adapter AMBU Substitute 0334M with 2952/10	CL-10407-06-10	AMBU A/S
2.155032	SNAP-CLIP Adapter for banana-plug cables pouch of 10 pcs	0334M	AMBU A/S
2.155030	Abrasive pads CARDIO-PREPS, pouch of 50 pcs	09-2121M-50	AMBU A/S
2.155000	Suction electrode 4mm	SUAG0024/6	SPES MEDIC
2.155060	Replacement bulb for suction electrode 2.155000	See SCHILLER AG REF No.	SCHILLER AG
2.155020	Adult clamp extremity electrode, set of 4 pcs	n/a	SPES MEDIC
2.158000	Electrode gel 50 ml net 4.00	ECGGEL50SPE	SPES MEDIC
2.158006	ECG electrode contact spray, bottle 250 ml	See SCHILLER AG REF No.	SCHILLER AG
2.000041	Set of adult ECG electrodes incl. 6 suction electrodes, 4 clamp extremity electrodes and 1 ECG electrode gel 50ml	EKG-KIT SCHILLER AG	SPES MEDIC
2.000052	Set of children ECG electrodes incl. 6 suction electrodes, 4 clamp extremity electrodes and 1 ECG electrode gel 50ml	ECG-KIT FOR SAG CHILDREN	SPES MEDIC
2.160017	Dust cover for AT-102 G2	See SCHILLER AG REF No.	SCHILLER AG
2.101125	Trolley X1 with mounting bracket	n/a	Multix Solutions s.r.l.
2.101118	Drawer for trolleys X1, X2	See SCHILLER AG REF No.	SCHILLER AG
2.101119	Basket translucent for trolleys X1, X2	See SCHILLER AG REF No.	SCHILLER AG
2.101121	Holder Barcodescanner for trolleys X1, X2	See SCHILLER AG REF No.	SCHILLER AG
2.101122	Holder suction pump Ergo Vag for trolley X1	See SCHILLER AG REF No.	SCHILLER AG
2.101130	ECG cable support for trolley X1	See SCHILLER AG REF No.	SCHILLER AG



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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: 2.155031: Biotabs ECG Electrodes Was replaced by: 2.155034: White Sensor EKG Tabs Added the 2.155035 as a replacement for 2.155032	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
Update to TMPL-0085 Rev.06 Added harmonized standard	06	2021-07-21