	<b>Declaration of Conformity</b>		<b>SCHILLER</b> <small>The Art of Diagnostics</small>
	CH-DHF-2871 Rev. 03	Effective Date : 24 Sep 2020	

## 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	
<b>Trade Name</b>	CARDIOVIT AT-180
<b>Product Type</b>	Multichannel ECG
<b>Intended Purpose</b>	The CARDIOVIT AT-180 is a multichannel ECG device intended to be used by trained medical professionals in healthcare facilities for the cardiological diagnosis in adult and paediatric patients
<b>Risk Class acc. To Annex II MDD</b>	Ila
<b>GMDN Code</b>	16231
<b>REF Number</b>	3.920570 (as part of 0A.110000 complete)
<b>Standards Applied</b>	IEC 60601-1: 2012 IEC 60601-1-2: 2014 IEC 60601-1-6: 2010/AMD1: 2013 IEC 60601-2-25: 2011 IEC 62304: 2006/AMD1: 2015 IEC 62366-1: 2015/COR1: 2016 EN ISO 14971: 2012 EN ISO 10993-1: 2010 EN ISO 10993-5: 2009 EN ISO 10993-10: 2014 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)*.

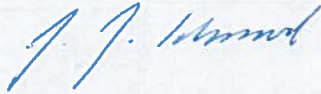
This declaration of conformity is issued under the sole responsibility of Schiller AG.

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




Johann-Jakob Schmid

Senior Vice President

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**Appendix 01 Accessories Compatible to the Device Covered by This Declaration**

Accessory Name	Legal Manufacturer	REF Number
<b>ECG</b>		
10-wire patient cable IEC, 2m with banana plug, RAL 7032	SAG	2.400070
10-wire patient cable IEC, 2m with banana plug, RAL 7035	SAG	2.400180
10-wire patient cable IEC, 3.5m clip, RAL 7032	SAG	2.400095
10-wire patient cable IEC, 3.5m clip, RAL 7035, RAL 7032	SAG	2.400175
10-wire patient cable AHA, 2m with banana plug	SAG	2.400071
10-wire patient cable AHA, 2m with banana plug, RAL 7035	SAG	2.400179
10-wire patient cable AHA, 3.5m clip, RAL 7032	SAG	2.400104
10-wire patient cable AHA, 3.5m clip, RAL 7035	SAG	2.400178
14-wire patient cable IEC, 3.5 m with banana plug	SAG	2.400142
14-wire patient cable IEC, 3.5m clip	SAG	2.400140
14-wire patient cable AHA, 3.5m with banana plug	SAG	2.400141
14-wire patient cable AHA, 3.5m clip	SAG	2.400139
EI-Lt.IEC Clip Balanced 4 Set	Bernd Richter	2.410099
EI-Lt.IEC B'St Balanced 4 Set	Bernd Richter	2.410090
<b>Electrodes, Gel and abrasive Pads</b>		
Set of adult ECG electrodes including 6 suction, 4 clamp extremity electrodes	SPES MEDICA	2.000041
Set of children ECG electrodes including 6 suction electrodes, 4 clamp extremity electrodes	SPES MEDICA	2.000052
Suction electrode 4mm	SPES MEDICA	2.155000
Adult clamp extremity electrode, set of 4 pcs	SAG	2.155020
Replacement bulb for suction electrode 2.155000	SAG	2.155060
Electrode gel 50 ml	SPES MEDICA	2.158000
ECG electrode contact spray, bottle 250 ml	SAG	2.158006
Stress test electrodes	AMBU A/S	2.155025
White Sensor EKG Tabs	AMBU A/S	2.155034
Snap clip adapters for banana plug, 10 pcs	AMBU A/S	2.155032
Snap-Clip-Adapter AMBU _Substitute 0334M with 2952/10	AMBU A/S	2.155035
Abrasive pads CARDIO-PREPS, pouch of 50 pcs	AMBU A/S	2.155030
<b>Other Device Accessories</b>		
3P 2.5m Netzkabel CH, 1x abgew	QUEEN PUO	2.300003
3P 2.5m Netzkabel D, 2x abgew	QUEEN PUO	2.300005
3P 2.5m Netzkabel HG US, 1xabge	QUEEN PUO	2.300024
3P 2.5m Netzkabel UK, 2x abgew	QUEEN PUO	2.300004
3P 2.5m Netzkabel CN, abgew	QUEEN PUO	2.300014
3P 2.5m Netzkab. Japan 1xabge	QUEEN PUO	2.300016
3P Netzkabel Brasilien, 1x abge	QUEEN PUO	2.300025
3P 2.5m Netzkabel CH, gerade	QUEEN PUO	2.300000
3P 2.5m Netzkabel D, gerade	QUEEN PUO	2.300002
3P 2.5m Netzkabel UK, gerade	QUEEN PUO	2.300011
3P 2.5m Netzkabel USA, gerade	QUEEN PUO	2.300012
Grounding cable	SAG	2.310005
QRS trigger cable	SAG	4.520564
Z-fold BPA-free thermal paper (210x280 mm) with paper maker on top	SAG	2.157039
Trolley X3 incl. Bascet for AT-180	MULTIX Solutions	2.101169

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**Device Dependent Declaration of Conformity Revision History**

Brief Description of Change	Version	Release Date
<p>The following article was end of life:</p> <ul style="list-style-type: none"> <li>• 2.155031: Biotabs ECG Electrodes</li> </ul> <p>Was replaced by:</p> <ul style="list-style-type: none"> <li>• 2.155034: White Sensor EKG Tabs</li> </ul> <p>Added the 2.155035 as a replacement for 2.155032</p>	03	Effective Date
Correct entry REF no., list all possible complete sales variants in future.	02	05 Nov 2019
First introduce to CE-mark region	01	31 Oct 2019