



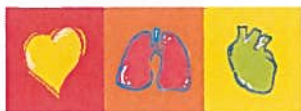
## Declaration of Conformity

**Manufacturer:** Schiller AG  
Altgasse 68, 6341 Baar, Switzerland  
**Manufacturing Site(s):** Schiller AG  
Altgasse 68, 6341 Baar, Switzerland  
**Product:** Electrocardiograph  
**Risk Class:** IIa  
**Type:** CARDIOVIT AT-1 G2

**Standards applied:** IEC 60601-1  
IEC 60601-2-25  
IEC 60601-1-2  
IEC 62304  
IEC 62366  
ISO 14971

### List of Products covered by the Declaration of Conformity of CARDIOVIT AT-1 G2:

|          |                                                                                                                        |
|----------|------------------------------------------------------------------------------------------------------------------------|
| 3.911050 | CARDIOVIT AT-1 G2                                                                                                      |
| 2.000041 | Set of adult ECG electrodes including 6 suction<br>4 clamp extremity electrodes and 1 ECG electrode gel                |
| 2.000052 | Set of children ECG electrodes including 6 suction electrodes,<br>4 clamp extremity electrodes and 1 ECG electrode gel |
| 2.155025 | Blue Sensor Disposable ECG Electrode, ø 48mm                                                                           |
| 2.155031 | SCHILLER Biotabs Ag/AgC, disposable electrodes for resting ECG                                                         |
| 2.155032 | SNAP-CLIP Adapter for banana-plug cables                                                                               |
| 2.157044 | Z-fold thermal chart paper<br>thermosensitive, z-folded, 1 package, 80 mm wide                                         |
| 2.157045 | Thermal chart paper AT-1 G2, roll<br>thermosensitive, 1 roll, 80 mm wide                                               |
| 5.107001 | ETM Software AT-1 G2 (ECG Treatment Module)                                                                            |
| 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                                                                             |
| 2.300014 | Mains cable, China, 90° angled                                                                                         |



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|          |                                                 |
|----------|-------------------------------------------------|
| 2.300016 | Mains cable black, Japan, 90° angled            |
| 2.300024 | Mains cable USA hospital grade, 2,5m, 90°angled |
| 2.300025 | Mains cable Brazil, 90° angled                  |
| 2.310320 | Grounding cable 3m, POAG to 4.8mm flat plug     |
| 2.400070 | 10-wire patient cable IEC 2m, banana plug type  |
| 2.400095 | 10-wire patient cable IEC, 3.5m clip-type       |
| 2.400071 | 10-wire patient cable AHA 2m, banana plug type  |
| 2.400104 | 10-wire patient cable, clip type, 3.5m, AHA     |

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*.

The conformity of the full quality assurance system is certified by:

TÜV SÜD Product Service GmbH, ID 0123

Ridlerstrasse 65, 80339 Munich

Germany

The identification number of the notified body for implementation of the procedure set out in Annex II to the above mentioned Directive is 0123.

The device of the 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 19 March 2021 and supersedes any declaration issued previously for the same product.

**Signed for on behalf of:** Schiller AG

Date of Issue: 05 May 2017

Place of Issue: Baar, Switzerland

Zhenrong Yu, MD, PhD

Vice President, Regulatory Affairs and Quality Assurance

**SCHILLER AG**

Altgasse 68

CH-6341 Baar/Switzerland