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|  | Declaration of Conformity MDD | | SCHILLER <small>The Art of Diagnostics</small> |
| | CH-DHF-0801 Rev. 04 | 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 | |
|--|--|
| Trade Name | CARDIOVIT AT-1 G2 |
| Product Type | Electrocardiograph |
| Intended Purpose | The CARDIOVIT AT-1 G2 is a 12-lead ECG device intended to be used by trained medical professionals in healthcare facilities for cardiological diagnosis in adult and paediatric patients. ECG analysis is complemented with algorithms that provide measurement results, data, graphic presentation and interpretation for review by the user. |
| Risk Class acc. To Annex II MDD | Ila |
| GMDN Code | 16231 |
| REF Number | 3.911050 (part of 0A.107000 complete) 3.911060 (part of 0A.107100 complete) |
| Standards Applied | IEC 60601-1: 2012 IEC 60601-1-2: 2014 IEC 60601-2-25: 2011 IEC 62304: 2006 + A1: 2015 IEC 62366: 2007 + A1: 2014 IEC 60601-1-6: 2013 EN ISO 14971: 2012 DIN EN ISO 10993-1: 2018 EN ISO 10993-5: 2009 DIN 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 |
|---|---------------------------|-------------------|
| Set of adult ECG electrodes including 6 suction 4 clamp extremity electrodes and 1 ECG electrode gel | SPES MEDIC | 2.000041 |
| Set of children ECG electrodes including 6 suction electrodes, 4 clamp extremity electrodes and 1 ECG electrode gel | SPES MEDIC | 2.000052 |
| Blue Sensor Disposable ECG Electrode, ø 48mm | 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 | AMBU A/S | 2.155032 |
| Z-fold thermal chart paper thermosensitive, z-folded, 1 package, 80 mm wide | SAG | 2.157058 |
| ETM Software AT-1 G2 (ECG Treatment Module) | SAG | 5.107001 |
| Mains cable AC Swiss, 90° angled | QUEEN PUO | 2.300003 |
| Mains cable UK, 90° angled | QUEEN PUO | 2.300004 |
| Mains cable Schuko Europe 2,5m, 90° angled | QUEEN PUO | 2.300005 |
| Mains cable, China, 90° angled | QUEEN PUO | 2.300014 |
| Mains cable black, Japan, 90° angled | QUEEN PUO | 2.300016 |
| Mains cable USA hospital grade, 2,5m, 90°angled | QUEEN PUO | 2.300024 |
| Mains cable Brazil, 90° angled | QUEEN PUO | 2.300025 |
| Grounding cable 3m, POAG to 4.8mm flat plug | SAG | 2.310320 |
| 10-wire patient cable IEC 2m, banana plug type | SAG | 2.400070 |
| 10-wire patient cable AHA 2m, banana plug type | SAG | 2.400071 |
| 10-wire patient cable IEC, 3.5m clip-type | SAG | 2.400095 |
| 10-wire patient cable, clip type, 3.5m, AHA | SAG | 2.400104 |
| 10-wire patient cable IEC, 3,5m clip | SAG | 2.400175 |
| 10-wire patient cable IEC, 2m with banana plug | SAG | 2.400180 |
| 10-wire patient cable AHA, 3,5m clip | SAG | 2.400178 |
| 10-wire patient cable AHA, 2m with banana plug | SAG | 2.400179 |

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Device Dependent Declaration of Conformity Revision History

| Brief Description of Change | Version | Release Date |
|---|---------|-------------------------|
| First introduce to CE-mark region (05.05.2017) & resigned... | 01 | Ref. MC Release Date |
| Update to MC TMPL Added 60601-1-6, 10993-10, updated 13485: 2016 standard | 02 | See MC Release Date |
| Update for new device variant 3.911060 Update for additional accessories 2.400175, 2.400178, 2.400179 and 2.400180 Update standard 10993-1, correct standard 10993-10 | 03 | 30 Jan 2020 |
| 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 |