# CS-200 Office
# EU Declaration of Conformity (MDD)
# Rev. 09

SCHILLER
The Art of Diagnostics

**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 CS-200 Office | |
| **Product Type** | Electrocardiograph | |
| **Intended Purpose** | The CARDIOVIT CS-200 Office is a multichannel electrocardiograph device intended to be used by trained medical professionals or under direct supervision of a licensed health care practitioner, in hospitals, clinics, physician offices and outreach centers for cardiopulmonary diagnosis in adult and pediatric patients. The ErgoSpiro option additionally is a cardio-pulmonary exercise system providing breath-by-breath measurements of flow, oxygen uptake and carbon dioxide production. | |
| **Risk Class acc. to Annex IX MDD** | IIa | |
| **GMDN Code** | 16231 | |
| **REF Number** | REF # | Description |
| | 0A.103000 | CARDIOVIT CS-200 Office Blue (Bluetooth) |
| | 0A.103050 | CARDIOVIT CS-200 Office (for replacement delivery) |
| | 0A.103100 | CARDIOVIT CS-200 Office (USB) |
| | 0A.103200 | CARDIOVIT CS-200 Office (ErgoSpiro) |
| **Standards Applied** | EN ISO 14971:2012 (ISO 14971:2019)<br>EN ISO 13485:2016/AC:2018 (ISO 13485:2016)<br>EN 60601-1:2006/A1:2013 (IEC 60601-1:2012)<br>EN 60601-1-2:2015 (IEC 60601-1-2:2014)<br>EN 60601-2-25:1995/A1:1999 (IEC 60601-2-25:2011)<br>EN 62366:2008 (IEC 62366:2007/A1:2014)<br>EN 60601-1-6:2010 (IEC 60601-1-6:2013)<br>EN 62304:2006/AC:2008 (IEC 62304:2015)<br>IEC 60529:2013<br>EN ISO 15223-1:2016 (ISO 15223-1:2016)<br>EN ISO 10993-1:2009 (ISO 10993-1:2003)<br>EN ISO 10993-5:2009 (ISO 10993-5:2009)<br>EN ISO 10993-10:2010 (ISO 10993-10:2010) | |

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 and Appendix 02 for components and spare parts.

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.

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.

CE 0123

This declaration supersedes any declaration issued previously for the same product.

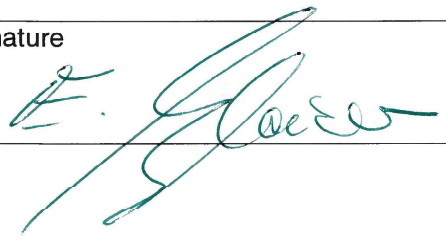
**Signed for on behalf of:** SCHILLER AG

Date of Issue: 2023-02-28
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY MANAGEMENT

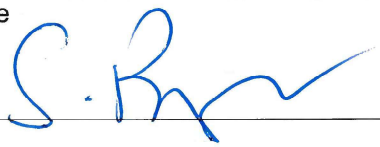
Signature



Name: STEFAN BIGLER

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 (Description IfU SCHILLER AG) | REF No. as per Label | Legal Manufacturer |
|---|---|---|---|
| 3.920725 | MS-12 USB | See SCHILLER AG REF No. | SCHILLER AG |
| 2.310317 | Adapter cable for suction device | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400222 | 10-lead patient cable IEC snap type | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400223 | Patient cable 10-lead snap type AHA color code | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400224 | 10-wire patient cable AHA banana plug | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400225 | 10-wire patient cable banana plug IEC | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400226 | ECG 10-wire patient cable IEC dot clip / 10-wire patient cable for MS-12 ECG Recorder, snap type, IEC colour code. | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400227 | ECG 10-wire patient cable AHA dot clip / 10-wire patient cable for MS-12 ECG Recorder, snap type, AHA colour code. | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400228 | 10-wire patient cable clip type IEC | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400229 | 10-wire patient cable clip type AHA | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400330 | ECG 10-wire patient cable IEC banana plug / 10-wire patient cable for MS-12 ECG Recorder, banana plug, IEC colour code | See SCHILLER AG REF No. | SCHILLER AG |
| 2.400331 | ECG 10-wire patient cable AHA banana plug / 10-wire patient cable for MS-12 ECG Recorder, banana plug, AHA colour code | See SCHILLER AG REF No. | SCHILLER AG |

**Appendix 02 Components and spare parts compatible to the device(s) covered by this declaration:**

| SCHILLER AG REF No. | Components / spare parts | REF No. as per Label |
|---|---|---|
| 2.300000 | Mains cable Swiss type, straight | See SCHILLER AG REF No. |
| 2.300002 | Mains cable Schuko Europe, straight | See SCHILLER AG REF No. |
| 2.300011 | Mains cable UK, straight | See SCHILLER AG REF No. |
| 2.300012 | Mains cable USA hospital grade, 2,5m straight | See SCHILLER AG REF No. |
| 2.300014 | Mains cable, China, 90° angled | See SCHILLER AG REF No. |
| 2.300016 | Mains cable black, Japan, 90° angled | See SCHILLER AG REF No. |
| 2.300025 | Mains cable Brazil, 90° angled | See SCHILLER AG REF No. |
| 4.150391 | 24" Monitor | P2422H |
| 4.150392 | OptiPlex 7080 | OptiPlex 7080 MFF XE XCTO |
| 4.150406 | OptiPlex 7000 | OptiPlex 7000 XE Micro |

**Device Dependent Declaration of Conformity Revision History**

| Brief Description of Change | Version | Release Date |
|---|---|---|
| CARDIOVIT CS-200 Office (MS-12 blue version) | 01 | 04 April 2019 |
| Change to new template<br>With ErgoSpiro-option | 02 | 19.Sep.2019 |
| - Adapt intended purpose<br>- Addition of the device dependent revision history 02<br><br>Deletion of the template revision history | 03 | 23.Octobre.2019 |
| The following article was end of life:<br>• 2.155031: Biotabs ECG Electrodes<br><br>Was replaced by:<br>• 2.155034: White Sensor EKG Tabs | 04 | Effective Date |
| Update to TMPL-0085 Rev.06<br>Referenced harmonized standards | 05 | 2021-07-21 |
| Addition of Biocompatibility standards for accessories:<br>• EN ISO 10993-1: 2009<br>• EN ISO 10993-5: 2009<br>• EN ISO 10993-10: 2010<br><br>Remove MS-12 blue from list of accessories (see DoC of MS-12 blue)<br>Remove of accessories from third parties:<br>• 2.000041 ECG Kit<br>• 2.155025 Ambu BlueSensor R ECG Electrodes<br>• 2.155034 White Sensor EKG Tabs<br><br>Split Appendix in part 01 (accessories and devices compatible) and 02 (components and spare parts) | 06 | 2021-11-11 |
| Addition of the following parts:<br>- 4.150391 24" Monitor<br>- 4.150392 OptiPlex 7080 | 07 | 2021-11-19 |
| Update to new template TMPL SAG Word Form vers. 3<br>Removed discontinued REF numbers 0A.103000, 0A.103010<br>Add Amendment version for EN 60601-1:2006/A1:2013<br>Add Amendment of 60601-2-25/A1:1999<br>Add international version of ISO 13485:2016<br>Add EN ISO 15223-1:2016<br>Add international version of ISO 10993-1:2003, ISO 10993-5:2009, ISO 10993-10:2010 | 08 | 2022-07-21 |
| Add AC:2018 to EN ISO 13485:2016<br>Add 4.150406 OptiPlex 7000 XE Micro<br>Remove 2.300003, 2.300004, 2.300005, 2.300024 | 09 | 2023-02-28 |