SCHILLER
The Art of Diagnostics

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SCHILLER AG Manufacturer's Declaration Regulation (EU) 2023/607

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**SCHILLER AG**
Manufacturer address and contact details	**Altgasse 68, CH-6341 Baar, Switzerland**
Single Registration Number (SRN)	**CH-MF-000012722**
Swiss Single Registration Number (CHRN)	**CHRN-MF-20000372**
Authorised Representative name	**SCHILLER Medizintechnik GmbH**
Authorised Representative address and contact details	**Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany**
Single Registration Number (SRN)	**DE-AR-000006934**
Notified body name, number	**TÜV SÜD Product Service GmbH, 0123**
Directive Certificate number(s) to which this confirmation is made	**G1 041505 0120 Rev.00**
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	**16 April 2024**
End date of extended transition period	**31 December 2028**

We, as the manufacturer declare under our sole responsibility, the listed **devices** below are following the conditions listed in Article 120 (3c) of the MDR for continued placing on the market and putting into service.

Schedule of Devices for which the declaration is valid:

- **Tempus LS**: 3.940590
- **FRED Easyport plus**: 3.940060, 3.940063, 3.940066
- **ARGUS PRO LifeCare 2**: 3.940542, 3.940543
- **BR-102 plus**: 3.900470/ **BR-102 plus PWA**: 3.900480
- **BP-200 plus**: 3.930300, 3.930301, 3.930305
- **MedilogAR**: 3.920740, 1A.306000
- **SPIROVIT SP-1 G2**: 3.911120
- **MS-12 blue**: 3.920720
- **CARDIOVIT CS-200 Excellence** (including **ErgoSpiro**-option): 3.920280 (0.035000, 0.035100)
- **CARDIOVIT CS-200 Office** (including **ErgoSpiro**-option): 0A.103000, 0A.103050, 0A.103100, 0A.103200
- **CARDIOVIT AT-1 G2**: 3.911050/ **seca CT8000i-2** (SECA): 3.911060
- **CARDIOVIT AT-180**: 3.920570
- **CARDIOVIT AT-102 G2**: 3.912410, 3.912417, 3.912418, 3.912416, 3.912419 / **seca CT8000P-2** (SECA): 3.912421
- **CARDIOVIT FT-1**: 3.900863, **CRO**-variant: 3.900865 / **seca CardioPad-2** (SECA): 3.900870
- **CARDIOVIT MS-2015**: 3.900829, 3.900830, 3.900833

1. **Directive Certificate** as listed above:
   - covering the listed devices was valid on 26 May 2021 and have not been withdrawn.
   - formal applications to the notified body/bodies in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made to a notified body no later than 26 May 2024 for the devices listed or its substitutes and written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
2. **A Quality Management System (QMS)** in accordance with Article 10(9) MDR is in place.
3. **Devices listed:**
   - The devices continue to comply with the MDD as per respective EU MDD declaration of conformity, maximum to end of transition period, if not withdrawn sooner, upon market availability of substitute and/or MDR transition
   - There are no significant changes in the design and intended purpose.
   - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer SCHILLER AG**:**

Date: 2024-06-28

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Change history: 2024-03-13: First version, 2024-06-28: added MS-2015 to Schedule of Devices