

	Declaration of Conformity		SCHILLER <small>The Art of Diagnostics</small>
	CH-DHF-1076 Rev. 02	Effective Date : 02 Oct 2019	

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	SEMA
Product Type	Stand-Alone Medical Software
Intended Purpose	<p>SEMA is a diagnostic data management system and PC-ECG device, intended to be used</p> <ul style="list-style-type: none"> - For the recording, reception, viewing, analysis, manual editing, printing and storing of digitized cardiopulmonary and patient demographic records, consisting of measurements, text, waveforms, and PDF reports - By trained medical professionals and service technicians - In hospitals, physicians' offices, and other facilities providing patient care - With patients of all genders, races, and ages
Risk Class acc. To Annex II MDD	Ila
GMDN Code	16231/57967
REF Number	5.303001 5.602031 5.602030 5.602005 5.602020 5.602013 5.602012 5.602011 5.602010 5.602001 5.602002 5.602000
Standards Applied	IEC 62304: 2006 IEC 62366-1: 2007 IEC 60601-1-6: 2010 EN ISO 14971: 2007 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.

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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.

Signed for on behalf of: Schiller AG

Place of Issue: Baar, Switzerland



Johann-Jakob Schmid

Senior Vice President

