



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 MS-2010

Standards applied:

IEC 60601-1
IEC 60601-2-25
IEC 60601-1-2
ISO 14971

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.



SCHILLER
The Art of Diagnostics

Signed for on behalf of: Schiller AG

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Place of Issue: Baar, Switzerland

Zhenrong Yu, MD, PhD

Global Head of Regulatory Affairs and Quality Assurance

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