SCHILLER
The Art of Diagnostics

Declaration of Conformity

Manufacturer:	Schiller AG Altgasse 68, 6341 Baar, Switzerland
Manufacturing Site(s):	Schiller AG Altgasse 68, 6341 Baar, Switzerland
Product:	Holter Analysis System
Risk Class:	IIa
Type:	Medilog DARWIN 2

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.

Signed for on behalf of: Schiller AG

Date of Issue: 16 March 2016

Place of Issue: Baar, Switzerland

SCHILLER AG
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Global Head of Regulatory Affairs and Quality Assurance