ForaCare Suisse AG

EU Declaration of Conformity

We, ForaCare Suisse AG,

Neugasse 55, 9000 St. Gallen, Switzerland

as Legal Manufacturer, declare under our sole responsibility that the product

Product Name	:	Blood Glucose Plus Blood Pressure Monitoring System
Product Model	:	FORA D40a FORA D40g FORA D40b FORA D40 pro
Classification	:	IVDD 98/79/EC, Annex II, List B; MDD 93/42/EEC (amended with 2007/47/EC), Annex IX, Section 3, Rule 10, Class IIa
Conformity Assessment Route	:	IVDD 98/79/EC, Annex IV excluding sections 4 & 6; MDD 93/42/EEC (amended with 2007/47/EC), Annex II excluding section 4
EC Certificate Number	:	IVDD: V1 092658 0004 Rev. 02; MDD: G1 092658 0006 Rev. 01
Certificate Valid Until	:	IVDD: 2023-03-04; MDD: 2023-10-10
CE Mark	:	**CE 0123**
Notified Body	:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany
GMDN Code	:	63087

to which this declaration relates is in conformity with the following standard(s) or other normative document(s)：

IVDD:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15197:2015	In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

ForaCare Suisse AG

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 18113-4:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
EN ISO 18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

2011/65/EU	On the restriction of the use of certain hazardous substances in electrical and electronic equipment.
98/79/EC	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

MDD:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 60601-1:2006 +A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 62304:2006+A1:2015	Medical device software. Software life-cycle processes
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 1041:2008 +A1:2013	Information supplied by the manufacturer of medical devices.
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements.
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type.
EN 1060-3:1997 +A2:2009	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.
EN 1060-4:2004	Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

FORA®
ForaCare Suisse AG

EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
2011/65/EU	On the restriction of the use of certain hazardous substances in electrical and electronic equipment.
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

The objective of the declarations above is to conform that above-mentioned product(s) meet the provisions of the “Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices”, “Council Directive 93/42/EEC of 14 June 1993 concerning medical devices” and “Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment”.

St. Gallen, February 27, 2020
Place, Date of Issue

Ty-Minh Tan, C.E.O.