ForaCare Suisse AG

EU DECLARATION OF CONFORMITY

We, ForaCare Suisse AG, Neugasse 55, 9000 St. Gallen, Switzerland as Legal Manufacturer, declare on our sole responsibility that the product

Product Name	: Multi-functional Monitoring System
Product Model	: GD82
Brand	: FORA 6 Connect, FORA 6 Duo
Classification	: IVDD 98/79/EC, Annex II, List B
Conformity Assessment Route	: IVDD 98/79/EC, Annex IV excluding sections 4 & 6
EC Certificate Number	: V1 092658 0004 Rev. 06
Certificate Valid Until	: 2025-05-26
CE Mark	: CE0123
Notified Body	: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany
GMDN Code	: 56675
EU Authorized Representative	: MedNet EC-REP GmbH Borkstraße 10, 48163 Muenster, Germany

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

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	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 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
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 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN IEC 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)
EN 62304:2006+A1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 301 489-1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
EN 300 328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
(EU)2015/863	The restriction of the use of certain hazardous substances in electrical and electronic equipment.

The objective of the declarations above is to confirm 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”.

Sincerely,

Firmato digitalmente da: MATTHIAS JOHANN TY-MINH TAN

St. Gallen

Ty-Minh TAN

CEO

ForaCare Suisse AG

Signed in St. Gallen, Switzerland

Aug 23, 2023