FORA®
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	: Blood Glucose Control Solution
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	: 41819
EU Authorized Representative	: MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany

Model	ACS014	ACS015	ACS016	ACS017	ACS018	ACS019
Brand Name	FORA	FORA	FORA	FORA	FORA	FORA
				4SURE	4SURE	4SURE

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 14971:2012	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 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

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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

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,

ForaCare Suisse AG
Neugasse 55, 9000 St. Gallen
Switzerland
TEL:+41-71-220-1055
www.forecare.ch

Ty-Minh TAN
CEO
ForaCare Suisse AG

Signed in St. Gallen, Switzerland
May 25, 2022