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 List** :

| Product Name | Product Model | GMDN Code |
|---|---|---|
| β-Ketone Test Strip | ACS053 | 53334 |
| Uric Acid Test Strip | ACS057 | 53586 |
| Total Cholesterol Test Strip | ACS055 | 53362 |

**Brand Name** : FORA 6

**Classification** : IVDD 98/79/EC, Self-Testing

**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

**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 |

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|---|---|
| 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 17511:2021 | In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials |
| 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,


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Ty-Minh TAN

CEO

ForaCare Suisse AG

Signed in St. Gallen, Switzerland

Aug 23, 2023