



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 092658 0004 Rev. 03**

**Manufacturer: Foracare Suisse AG**

Neugasse 55  
9000 St. Gallen  
SWITZERLAND

## Product Category(ies): In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1\\_092658\\_0004\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:V1_092658_0004_Rev.03)

**Report no.:** TW2003003

**Valid from:** 2021-02-22

**Valid until:** 2023-03-04

**Date,** 2021-02-22

Christoph Dicks  
Head of Certification/Notified Body



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## Model(s):

1. **Blood Glucose Monitoring System**  
(GD83, GD85, GD86, FORA G30a, FORA G31a, FORA G31b, FORA G71a, FORA V30a, FORA V10, FORA G20, FORA DM10, FORA DM20a, FORA DM20b, FORA DM30a, FORA DM30b, FORA GD50a, FORA G40, FORA GD40a, FORA GD40b, FORA GD50b)
2. **Multi-functional Monitoring System**  
(GD81, GD82, GD40g, GD40h, GD84)
3. **Blood Glucose and  $\beta$ -Ketone Monitoring System**  
(GD87)
4. **Blood Glucose Test Strip**  
(ACS045, ACS047, ACS046, ACS040, ACS041, ACS042, ACS044, ACS043)
5.  **$\beta$ -Ketone Test Strip (ACS053, ACS052)**
6. **Total Cholesterol Test Strip (ACS055)**
7. **Uric Acid Test Strip (ACS057)**
8. **Blood Glucose Control Solution**  
(ACS017, ACS018, ACS019, ACS014, ACS015, ACS016)
9.  **$\beta$ -Ketone Control Solution**  
(ACS027, ACS028, ACS029)
10. **Total Cholesterol Control Solution (ACS030)**
11. **Uric Acid Control Solution (ACS031)**
12. **Blood Glucose, Hematocrit and Hemoglobin Test Strip**  
(ACS050, ACS051)
13. **Blood Glucose Plus Blood Pressure Monitoring System**  
(FORA D40a, FORA D40b, FORA D40g, FORA D40 pro)
14. **Conventional Midstream Type Pregnancy Test**  
(FORA PNC200, FORA PNC210)
15. **Conventional Strip Type Pregnancy Test**  
(FORA PNC300)
16. **Digital Pregnancy Test for Single Use**  
(FORA PNC110)
17. **Digital Pregnancy Test for Multiple Use**  
(FORA PNC100)

## Facility(ies):

ForaCare Suisse AG  
Neugasse 55, 9000 St. Gallen, SWITZERLAND