



Certificate

No. Q5 092658 0005 Rev. 04

Holder of Certificate: **ForaCare Suisse AG**

Neugasse 55
9000 St. Gallen
SWITZERLAND

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of
Blood Glucose Monitoring System, Multi-Functional Monitoring
System,
Blood Glucose and β -Ketone Monitoring System, Blood Glucose
Plus Blood Pressure Monitoring System,
Conventional Midstream Type Pregnancy Test, Conventional Strip
Type Pregnancy Test, Digital Pregnancy Test for Single Use, Digital
Pregnancy Test for Multiple Use, Hemoglobin A1c Analyzer,
Hemoglobin A1c Reagent Cartridge,
Blood Glucose Test Strip, Blood Glucose, Hematocrit and
Hemoglobin Test Strip, β -Ketone Test Strip, Total Cholesterol Test
Strip, Uric Acid Test Strip,
Blood Glucose Control Solution, β -Ketone Control Solution, Total
Cholesterol Control Solution, Uric Acid Control Solution,
Hemoglobin A1c Control Solution,
Lancing Device, Thermometer, Blood Pressure Monitor, Sterile
Lancets, Weight Scale, Digital Thermometer, Aneroid Blood
Pressure Kit, Temperature Monitor, Probe Cover and Reusable NIBP
Cuff,
Medical Information Management Application (for mobile devices),
TeleHealth System.

Production and Distribution of Sterile Lancets, Safety Lancets and
Disposable Insulin Pen Needles.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned
above has established and is maintaining a quality management system, which meets the
requirements of the listed standard(s). 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:Q5 092658 0005 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_092658_0005_Rev._04)

Report No.: TW2303002

Valid from: 2024-02-19

Valid until: 2027-02-18

Date, 2024-01-17

Christoph Dicks

Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **ForaCare Suisse AG**
Neugasse 55, 9000 St. Gallen, SWITZERLAND

see Scope of Certificate