



Certificate

No. Q5 092658 0005 Rev. 02

Holder of Certificate: **ForaCare Suisse AG**

Neugasse 55
9000 St. Gallen
SWITZERLAND

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of Lancing Device, Blood Glucose Monitoring System, Multi-functional Monitoring System, Blood Glucose and β -Ketone Monitoring System, 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, 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, Thermometer, Blood Pressure Monitor, TeleHealth Gateway, Sterile Lancets, Weight Scale, Digital Thermometer, Aneroid Blood Pressure Kit, Hemoglobin A1c Analyzer, Hemoglobin A1c Reagent Cartridge, Hemoglobin A1c Control Solution, Medical Information Management Application (for mobile devices), TeleHealth System, Temperature Monitor, Probe Cover and Reusable NIBP Cuff.

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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_092658_0005_Rev._02)

Report No.: TW2003003
Valid from: 2021-02-22
Valid until: 2024-02-18



Date, 2021-02-22

Christoph Dicks
Head of Certification/Notified Body



Product Service

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

See scope of certificate