



Product Service

Certificate

No. Q5 076477 0007 Rev. 02

Holder of Certificate: **BIORON Diagnostics GmbH**
 In den Rauhweiden 20
 67354 Römerberg
 GERMANY

Facility(ies): BIORON Diagnostics GmbH
 In den Rauhweiden 20, 67354 Römerberg, GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Nucleic Acid based in-vitro Diagnostics**

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

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_076477_0007_Rev.02

Report No.: 713188174

Valid from: 2020-09-06

Valid until: 2023-09-05

Date, 2020-08-27

Christoph Dicks
 Head of Certification/Notified Body