



Certificate

No. Q5 076477 0007 Rev. 03

Holder of Certificate: **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 and Associated Molecular Biological Raw Materials**

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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_076477_0007_Rev.03)

Report No.: 713216385_1

Valid from: 2021-11-23

Valid until: 2023-09-05

Date, 2021-11-23

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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): **BIORON Diagnostics GmbH**
In den Rauhweiden 20, 67354 Römerberg, GERMANY

Design and Development, Production and Distribution of Nucleic
Acid Based In-Vitro Diagnostics and Associated Molecular
Biological Raw Materials

BIORON GmbH
In den Rauhweiden 20, 67354 Römerberg, GERMANY

Design and Development, Production and Distribution of Molecular
Biological Raw Materials for Nucleic Acid Based In-Vitro
Diagnostics

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