





Product Service

Certificate

No. Q8 112754 0001 Rev. 00

Holder of Certificate: BIORON GmbH

In den Rauhweiden 20 67354 Römerberg GERMANY

Certification Mark:



Scope of Certificate: Provision of Reagents for the Production of Nucleic Acid Based In-Vitro Diagnostic Detection Kits and Distribution of

Nucleic Acid Based In-Vitro Diagnostic Detection Kits.

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:Q8 112754 0001 Rev. 00

Report No.: 713294779

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 Valid from:
 2023-09-06

 Valid until:
 2026-09-05

Date, 2023-08-16

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 GmbH

In den Rauhweiden 20, 67354 Römerberg, GERMANY

Provision of Reagents for the Production of Nucleic Acid Based In-Vitro Diagnostic Detection Kits and Distribution of Nucleic Acid

Based In-Vitro Diagnostic Detection Kits.

Parameters: ./.