



Product Service

Certificate

No. Q5 106240 0001 Rev. 01

Holder of Certificate: Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
07743 Jena
GERMANY

Facility(ies): Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, 07743 Jena, GERMANY

Abbott Rapid Diagnostics Jena GmbH
Löbstedter Straße 82, 07749 Jena, GERMANY

Abbott Rapid Diagnostics Jena GmbH
Löbstedter Straße 105, 07749 Jena, GERMANY

Certification Mark:



Scope of Certificate: Design, development, manufacture, distribution of in-vitro diagnostic products (reagents and instruments) and supporting products for immunological and nucleic acid based testing for the clinical areas of infectious diseases and hematology

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). See also notes overleaf.

Report No.: 713184815-03

Valid from: 2020-~~(10)~~(2e)

Valid until: ~~(10)~~(2e) - ~~(10)~~(2e)

Date, 2020-05-04

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