



Product Service

Certificate

No. Q5 107713 0001 Rev. 00

Holder of Certificate: Roche Diagnostics GmbH
 Roche Life Science
 Nonnenwald 2
 82377 Penzberg
 GERMANY

Facility(ies): Roche Diagnostics GmbH Roche Life Science
 Nonnenwald 2, 82377 Penzberg, GERMANY

 See Scope of Certificate

Certification Mark:



Scope of Certificate:

- Contract Manufacturing of IVDs
- Design and manufacturing of biologically, biotechnologically and/or chemically synthesized products, ingredients and kits used in medical devices, in vitro diagnostic devices, related products and in process controls.

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 107713 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_107713_0001_Rev_00)

Report No.: 713183945

Valid from: 2020-12-21
Valid until: 2023-12-20

Date, 2020-12-18

Christoph Dicks
 Head of Certification/Notified Body