



Certificate

No. Q5 107713 0001 Rev. 01

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:

- Provision of contract production services of IVD components and IVD finished products (Reagents)
- 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): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

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. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_107713_0001_Rev_01)

Report No.: 713304730

Valid from: 2023-12-21

Valid until: 2026-12-20

Date, 2023-12-12



Christoph Dicks

Head of Certification/Notified Body