



Certificate

No. Q5 125372 0001 Rev. 01

Holder of Certificate: **Centogene GmbH**
Am Strande 7
18055 Rostock
GERMANY

Facility(ies): **Centogene GmbH**
Am Strande 7, 18055 Rostock, GERMANY

Design & development, manufacturing and distribution of sample carrier papers for absorption and storage of human blood specimen as well as in-vitro diagnostic software solutions for rapid bioinformatic analysis and interpretation of human genetic variants

Certification Mark:



Scope of Certificate: **Design & development, manufacturing and distribution of sample carrier papers for absorption and storage of human blood specimen as well as in-vitro diagnostic software solutions for rapid bioinformatic analysis and interpretation of human genetic variants**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 125372 0001 Rev. 01

Report No.: 713405099

Valid from: 2026-06-23

Valid until: 2029-06-22

Date, 2026-05-27

Christoph Dicks
Head of Certification/Notified Body