ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 091170 0005 Rev. 00

Holder of Certificate: **Gentian AS**
Bjørnåsveien 5
1596 Moss
NORWAY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of immunological in-vitro diagnostic reagents, controls and calibration material**

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 091170 0005 Rev. 00

Report No.: 713204791

Valid from: 2021-05-07
Valid until: 2021-11-07

Date, 2021-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS
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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 091170 0005 Rev. 00

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):

Gentian AS
Bjørnåsveien 5, 1596 Moss, NORWAY

See Scope of Certificate

Parameters: ./.

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