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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 091170 0006 Rev. 01

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

Certification Mark:

Scope of Certificate: **Design, Development, Manufacturing and Distribution of Immunological In-Vitro Diagnostic Reagents, Controls and Calibration Material**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Brazil ANVISA, Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001239**

Effective Date: **2022-05-26**

Expiry Date: **2024-05-19**

Date of Issue: 2022-05-31

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: **Audit/Certification Criteria**

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):
Gentian AS
Bjørnåsveien 5, 1596 Moss, NORWAY

Facility Scopes:
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