



Certificate

No. Q5 091170 0005 Rev. 03

Holder of Certificate: **Gentian AS**

Bjørnåsveien 5
1596 Moss
NORWAY

Facility(ies):

Gentian AS

Bjørnåsveien 5, 1596 Moss, NORWAY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and Development, Manufacturing and Distribution of In-vitro diagnostic reagents for Immunochemistry and Infectious Immunology

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 091170 0005 Rev. 03

Report No.: 713317013

Valid from: 2024-05-07

Valid until: 2027-05-06

Date, 2024-05-03

Christoph Dicks

Head of Certification/Notified Body