

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
GA GENERIC ASSAYS GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

Details see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-04-20
Certificate Registration No.: SX 60128779 0001
An audit was performed. Report No.: 21283928 001
This Certificate is valid until: 2021-04-16

Certification Body



Date 2018-04-20



Dipl.-Ing. A. Fechner

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Certificate

Registration No.: SX 60128779 0001
Report No.: 21283928 001

Organization: GA GENERIC ASSAYS GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
Deutschland

Scope: Design and development, manufacturing and sales of
in vitro diagnostic devices with immunological
reaction systems consisting of reagents, kits and
analyzers with integrated software for the detection
and evaluation of infection and autoimmune diseases,
inflammatory parameters and endocrine disorders

Certification Body



Date: 2018-04-20




Dipl.-Ing. A. Fechner