

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1799112-1
Certificate Holder: GA Generic Assays GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
Germany

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1152123-40
Effective date: 2024-04-17
Expiry date: 2027-04-16
Issue date: 2024-04-12
Replaces certificate SX 1799112-1 issued 2021-04-16.

This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o GA Generic Assays GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow Germany	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.
/02	c/o GA Generic Assays GmbH Innovationszentrum Senftenberg Rudolf-Harbig-Str. 12 01968 Senftenberg Germany	Design and development, manufacturing of assay components.

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