



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Milenia Biotec GmbH

Versailler Str. 1 35394 Gießen Germany

Holds Certificate Number: MD 816381

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and development, manufacture and distribution of in-vitro diagnostic lateral flow tests for Point-of-Care use in inflammation and coagulation diagnostics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-04-02 Effective Date: 2025-08-04 Latest Revision Date: 2025-07-16 Expiry Date: 2028-08-03

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...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

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