

# 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

Latest Revision Date: 2025-07-16

Effective Date: 2025-08-04

Expiry Date: 2028-08-03

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