

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

**Mast Diagnostica GmbH**

Feldstrasse 20  
23858 Reinfeld  
Germany

Holds Certificate Number:

MD 644632

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

Design, development, manufacture of molecular biology, immunochemistry and microbiology in-vitro diagnostic kits and reagents for the diagnosis of autoimmune status and disease status. The manufacture of in-vitro diagnostic transport systems and the distribution of invitro diagnostic kits and swabs. Installation, servicing and distribution of in-vitro diagnostic analyser instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2015-12-21

Latest Revision Date: 2025-01-20

Effective Date: 2025-02-04

Expiry Date: 2028-02-03



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Certificate No: MD 644632

Location

Mast Diagnostica GmbH  
Feldstrasse 20  
Reinfeld  
23858  
Germany

Registered Activities

Design, development, manufacture of molecular biology, immunochemistry and microbiology in-vitro diagnostic kits and reagents for the diagnosis of autoimmune status and disease status. The manufacture of in-vitro diagnostic transport systems and the distribution of invitro diagnostic kits and swabs. Installation, servicing and distribution of in-vitro diagnostic analyser instruments.

Mast Diagnostica GmbH  
Grootkoppel 6  
Reinfeld  
23858  
Germany

Warehousing and incoming inspection of in-vitro diagnostic assays and transport systems.



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