

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 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 in-vitro diagnostic kits and swabs.

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 21/12/2015

Latest Revision Date: 03/02/2016

Effective Date: 04/02/2016

Expiry Date: 03/02/2019

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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 in-vitro diagnostic kits and swabs.

Mast Diagnostica GmbH  
Grootkoppel 6  
Reinfeld  
23858  
Germany

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



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