

# 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 in-vitro diagnostic kits and swabs.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-12-21

Latest Revision Date: 2019-01-02

Effective Date: 2019-02-04

Expiry Date: 2022-02-03

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 644632**

Location	Registered Activities
Mast Diagnostica GmbH Feldstrasse 20 Reinfeld 23858 Germany	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.

Original Registration Date: 2015-12-21  
Latest Revision Date: 2019-01-02

Effective Date: 2019-02-04  
Expiry Date: 2022-02-03

Page: 2 of 2

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 [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.