

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-12-21

Latest Revision Date: 2022-01-25

Effective Date: 2022-02-04

Expiry Date: 2025-02-03

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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 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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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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