

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

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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
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