

Certificate of Registration

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

This is to certify that:

BIOMED Labordiagnostik GmbH
Bruckmannring 32
85764 Oberschleissheim
Germany

Holds Certificate Number:

MD 674250

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

Manufacture and distribution of in vitro diagnostic medical devices (IVD) including reagents, calibration and control materials, combi test kits, rapid tests and instruments used for the in vitro examination of human sample materials.

Herstellung und Vertrieb von In-vitro-Diagnostika (IVD) wie Reagenzien, Kalibrier- und Kontrollmaterial, Kombi-Test-Kits, Schnellteste und Instrumente, die zur In-vitro-Untersuchung von menschlichem Probenmaterial verwendet werden.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-09-19

Latest Revision Date: 2021-01-08

Effective Date: 2021-01-15

Expiry Date: 2024-01-14

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