

# 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, combined test kits, rapid tests and instruments used for the in vitro examination of human sample materials as well as provision of associated services including target values determination for third party calibration and control materials.

Herstellung und Vertrieb von In-vitro-Diagnostika (IVD) einschließlich Reagenzien, Kalibrier- und Kontrollmaterialien, kombinierten Testkits, Schnelltests und Instrumenten für die In-vitro-Untersuchung von menschlichem Probenmaterial sowie Erbringung damit verbundener Dienstleistungen einschließlich der Bestimmung von Zielwerten für Kalibrier- und Kontrollmaterialien von Drittanbietern.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-09-19

Latest Revision Date: 2023-12-12

Effective Date: 2024-01-15

Expiry Date: 2027-01-14



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