



Certificate of Registration

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

This is to certify that: AESKU.DIAGNOSTICS GmbH & Co. KG

Mikroforum Ring 2 55234 Wendelsheim

Germany

Holds Certificate Number: MD 619745

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, installation, service and distribution of in-vitro-diagnostics test kits, in-vitro-diagnostics reagents, in-vitro-diagnostic instruments and software used in the diagnosis of autoimumune status and disease status (including infectious diseases and allergy).

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-10-10

Latest Revision Date: 2022-03-17

Effective Date: 2022-03-20 Expiry Date: 2025-03-19

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Certificate No: MD 619745

Location Registered Activities AESKU.DIAGNOSTICS GmbH & Co. KG Design, development, manufacture, installation, service and distribution of in-vitro-diagnostics test kits, in-vitro-Mikroforum Ring 2 diagnostics reagents, in-vitro-diagnostic instruments and 55234 Wendelsheim software used in the diagnosis of autoimumune status and Germany disease status (including infectious diseases and allergy). AESKU.DIAGNOSTICS GmbH & Co. KG Design, development, manufacture, installation, service and distribution of in-vitro-diagnostics test kits, in-vitro-Mikroforum Ring 3-5 diagnostics reagents, in-vitro-diagnostic instruments and 55234 Wendelsheim software used in the diagnosis of autoimumune status and Germany disease status (including infectious diseases and allergy).



Original Registration Date: 2014-10-10 Effective Date: 2022-03-20 Latest Revision Date: 2022-03-17 Expiry Date: 2025-03-19

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