

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, manufacturing and distribution of in-vitro diagnostic test kits and in-vitro diagnostic reagents used in the diagnosis of autoimmune status and disease status.

Previous certificate expired on 06/05/2017
Recertification audit ended 04/05/2017

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-10-10

Latest Revision Date: 2017-06-14

Effective Date: 2017-06-14

Expiry Date: 2019-02-28

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