

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1333941-1

Certificate Holder: B.R.A.H.M.S GmbH  
Neuendorfstr. 25  
16761 Hennigsdorf  
Germany

Scope: Design and development, manufacturing, distribution, installation and servicing of in-vitro diagnostic medical devices covering analyzers, software, reagents and test kits used in the detection, diagnosis and patient management of infectious diseases (sepsis), respiratory/ pulmonary/ neurological/ cardiovascular diseases, endocrinology and metabolic disorders and alcohol intoxication, cancer diseases and prenatal screening.  
Manufacturing and distribution of antibody solutions for in-vitro diagnostic purposes.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1156589-40

Effective date: 2024-07-05

Expiry date: 2027-07-04

Issue date: 2024-07-05

This certificate can be validated on <https://www.certipedia.com>

  
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