

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

MetaSystems Hard & Software GmbH
Robert-Bosch-Str. 6
68804 Altlußheim
Germany

Facility ID Number: F000307

Holds Certificate No:

MDSAP 689077

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture, Service and Support of Image Analysis Systems for Cytogenetics, Cytology, Pathology, Microbiology and Related Applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-11-29

Effective Date: 2023-07-19

Expiry Date: 2024-05-08



BSI Group America Inc. is an MDSAP recognised auditing organization