

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Chromsystems Instruments
& Chemicals GmbH
Am Haag 12
Gräfelfing
82166
Germany

Facility ID Number: F008788

Holds Certificate No:

MDSAP 838639

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

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-03-13

Effective Date: 2026-03-13

Expiry Date: 2027-10-18



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 838639**

Registered Scope:

Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for high-performance liquid chromatography [HPLC] and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.

Transferred from: TÜV SÜD

Certificate Number: QS6 057136 0013 Rev. 04



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An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 838639**

Location	Registered Activities
Chromsystems Instruments & Chemicals GmbH Am Haag 12 Gräfelting 82166 Germany Facility ID Number: F008788	Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for high-performance liquid chromatography [HPLC] and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.
Chromsystems Instruments & Chemicals GmbH Lochhamer Schlag 11a Gräfelting 82166 Germany Facility ID Number: F008788	Warehousing of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for high-performance liquid chromatography [HPLC] and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.
Chromsystems Instruments & Chemicals GmbH Lochhamer Schlag 11 Gräfelting 82166 Germany Facility ID Number: F008788	Order handling of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for high-performance liquid chromatography [HPLC] and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.

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