

Certificate of Registration

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

This is to certify that:

Chromsystems Instruments
& Chemicals GmbH
Am Haag 12
Gräfelfing
82166
Germany

Holds Certificate Number:

MD 838632

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for 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: Q5 057136 0012 Rev. 02

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-02-16

Latest Revision Date: 2026-02-16

Effective Date: 2026-02-16

Expiry Date: 2027-08-21

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Certificate No: MD 838632

Location	Registered Activities
Chromsystems Instruments & Chemicals GmbH Am Haag 12 Gräfelting 82166 Germany	Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for 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	Warehousing of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for 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	Order handling of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for 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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

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