

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 838647 R000

Manufacturer: Chromsystems Instruments & Chemicals GmbH

Address:

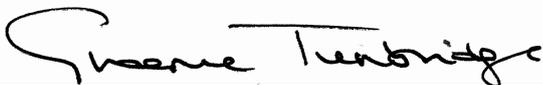
Am Haag 12
Gräfelfing
82166
Germany

Single Registration Number: DE-MF-000010089

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-03-04**

Current Issue Date: **2026-03-04**

Starting Validity Date: **2026-03-23**

Expiry Date: **2027-07-20**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0101 – Clinical Chemistry IVP 3003 - In vitro diagnostic devices which require knowledge regarding chromatography	Devices intended to be used in screening, diagnosis, staging or monitoring of cancer, screening, determination or monitoring of physiological markers for a specific disease, and monitoring of levels of medicinal products, substances or biological components.
Class B devices	Intended purpose
IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease.
IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components.
IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers	Devices intended to be used for screening, determination or monitoring of physiological markers.

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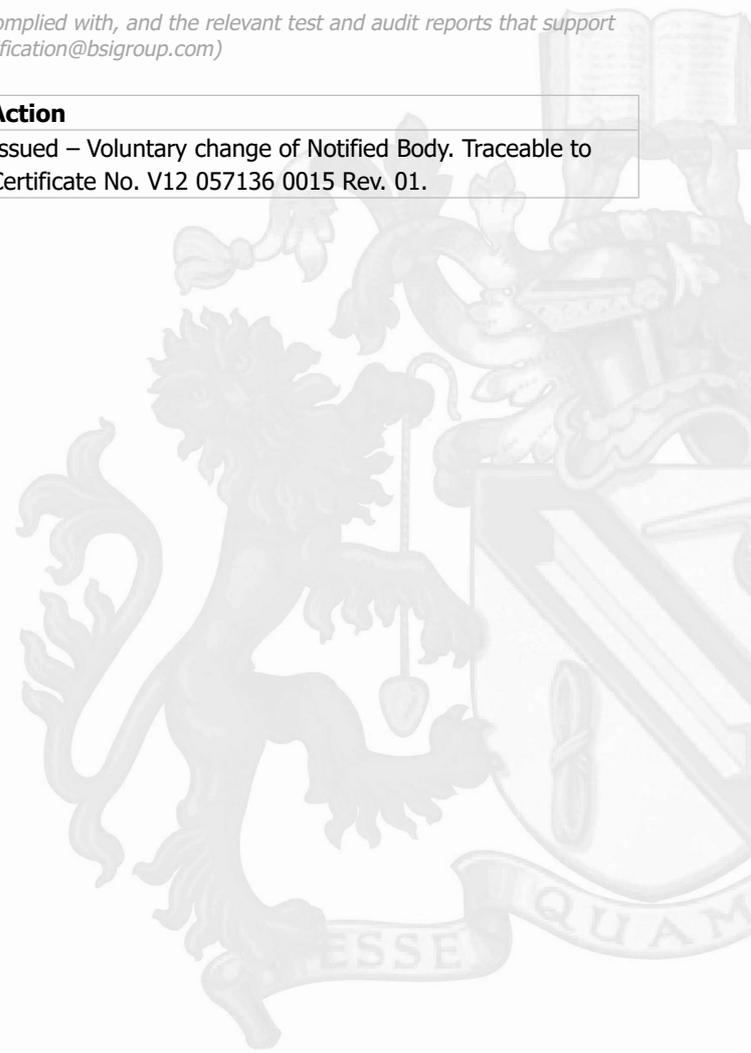
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30591221	Issued – Voluntary change of Notified Body. Traceable to Certificate No. V12 057136 0015 Rev. 01.



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