



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 057136 0015 Rev. 00

Manufacturer: **Chromsystems
Instruments & Chemicals GmbH**
Am Haag 12
82166 Gräfelfing
GERMANY

SRN Manufacturer: DE-MF-000010089

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12_057136_0015_Rev_00

Report No.: 713223054

Valid from: 2022-07-21

Valid until: 2027-07-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-21



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Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3003 - In vitro diagnostic devices which require knowledge regarding chromatography
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer
Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0605 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
The validity of this certificate depends on conditions and/or is limited to the following:	-none-