EU-Declaration of Conformity

Manufacturer	Chromsystems Instruments & Chemicals GmbH
Address	Am Haag 12 82166 Gräfelfing, Germany
SRN (single registration number)	DE-MF-000010089

Order No.	Device Description	EMDN Code
Basic UDI-DI: 4250317807006F		
80700/96	***MassChrom***® Biogenic Amines/Metabolites in urine Sample Prep Set Total Metanephrines (free + conjugated) with 96 SPE Well Plate	W01010499
80700/C	***MassChrom***® Biogenic Amines/Metabolites in urine Sample Prep Set Total Metanephrines (free + conjugated) with Sample Clean Up Columns	W01010499
80703	Hydrolysis Buffer	W01019099
80704	Internal Standard Mix	W0101050399
80739	**6PLUS1**® Multilevel Urine Calibrator Set ***MassChrom***® Total Metanephrines in urine	W0101050301
0376	***MassCheck***® Total Metanephrines Urine Control Level I	W0101050207
0377	***MassCheck***® Total Metanephrines Urine Control Level II	W0101050207

Basic UDI-DI: 4250317806006A		
80605	Neutralisation Buffer	W01019099
80675	Neutralisation Buffer	W01019099
80606	Wash Buffer 1	W01019099
80676	Wash Buffer 1	W01019099
80607	Wash Buffer 2	W01019099
80677	Wash Buffer 2	W01019099
80608	Elution Buffer	W01019099
80678	Elution Buffer	W01019099
80609	Dilution Buffer	W01019099
80679	Dilution Buffer	W01019099
80615	Tuning Mix	W0101050399

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Basic UDI-DI: 4250317800005C		
80000	***MassChrom®*** Biogenic Amines/Metabolites in urine Starter Set Chromatographic Platform	W01010499
80055	Sample Clean Up Columns ***MassChrom®*** Biogenic Amines/Metabolites in urine	W01019099
80056	Collection Plates ***MassChrom®*** Biogenic Amines/Metabolites in urine	W01019099
80057	96 SPE Well Plate ***MassChrom®*** Biogenic Amines/Metabolites in urine	W01019099
80058	Hydrolysis Plates ***MassChrom®*** Biogenic Amines/Metabolites in urine	W01019099
80059	Pierceable Adhesive Seals ***MassChrom®*** Biogenic Amines/Metabolites in urine	W01019099
80001	Mobile Phase A	W01019099
80002	Mobile Phase B	W01019099
80009	Rinsing Solution	W01019099
80100	Analytical Column	W01019099

Device Intended Purpose	The "***MassChrom®*** Biogenic Amines/Metabolites in urine Sample Prep Set Total Metanephrines (free + conjugated)" in combination with the "***MassChrom®*** Biogenic Amines/Metabolites in urine Starter Set Chromatographic Platform" is an *in vitro* diagnostic medical device for professional users in clinical laboratories for the quantitative determination of total (sum of free and conjugated metabolites) metanephrine, normetanephrine and 3-methoxytyramine in human urine samples via liquid chromatography with tandem mass spectrometry (LC-MS/MS). The "***MassChrom®*** Biogenic Amines/Metabolites in urine Sample Prep Set Total Metanephrines (free + conjugated)" is used for manual sample preparation. Analytic separation is carried out with the "***MassChrom®*** Biogenic Amines/Metabolites in urine Starter Set Chromatographic Platform" (order no. 80000), which provides the components required for chromatography. The assay is intended to be used for patients in whom the urinary levels of total metanephrine, total normetanephrine and total 3-methoxytyramine are of clinical importance, primarily as an aid to diagnosis and monitoring of suspected pheochromocytoma and paraganglioma. Furthermore, the assay is intended to be used for patients in whom the urinary levels of total normetanephrine and total 3-methoxytyramine are of clinical importance, as an aid to diagnosis and monitoring of suspected neuroblastoma.
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3h
GMDN Code	63892 "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

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Notified Body	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany	Identification No.	0123
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX Chapters I and III		
Certificates issued	EU Quality management System Certificate (IVDR) No. V12 057136 0015 Rev01		

Declarations

This EU declaration of conformity is issued under the sole responsibility of the manufacturer. The devices that are covered by the present declaration are in conformity with the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).

Following Common Specifications were considered as part of determining device conformity with the IVDR:

Not applicable as no Common Specifications exist for the concerned device.

Additional information	n/a

This EU declaration of conformity is issued by

Gräfelfing, August September 10th, 2024 Michael Meier, Managing Director	Gräfelfing, September 10th, 2024 Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:	September 09th, 2029	Version: 1.0

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