



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: 4250317806006A		
80600/C	MassChrom ® Biogenic Amines/Metabolites in urine Sample Prep Set Catecholamines, free Metanephrines, Serotonin with Sample Clean Up Columns	W01010499
80600/96	MassChrom ® Biogenic Amines/Metabolites in urine Sample Prep Set Catecholamines, free Metanephrines, Serotonin with 96 SPE Well Plate	W01010499
80600/480	MassChrom ® Biogenic Amines/Metabolites in urine Sample Prep Set Catecholamines, free Metanephrines, Serotonin with 96 SPE Well Plate	W01010499
80639	6PLUST [®] Multilevel Urine Calibrator Set MassChrom ® Catecholamines, free Metanephrines, Serotonin	W0101050301
0372	MassCheck ® Catecholamines, free Metanephrines, Serotonin Urine Control Level I	W0101050207
0373	MassCheck ® Catecholamines, free Metanephrines, Serotonin Urine Control Level II	W0101050207
80603	Adjustment Reagent	W01019099
80604	Internal Standard Mix	W0101050399
80604/5	Internal Standard Mix	W0101050399
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

Order No.	Device Description	EMDN Code
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
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	<p>The "MassChrom® Biogenic Amines/Metabolites in urine Sample Prep Set Catecholamines, free Metanephrines, Serotonin" in combination with the "MassChrom® Biogenic Amines/Metabolites in urine Starter Set Chromatographic Platform" is an <i>in vitro</i> diagnostic medical device for professional users in clinical laboratories for the quantitative determination of noradrenaline (syn. norepinephrine), adrenaline (syn. epinephrine), dopamine, free metanephrine, free normetanephrine, free 3-methoxytyramine and serotonin in human urine samples via liquid chromatography with tandem mass spectrometry (LC-MS/MS).</p> <p>The "MassChrom® Biogenic Amines/Metabolites in urine Sample Prep Set Catecholamines, free Metanephrines, Serotonin" 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 noradrenaline, adrenaline, dopamine, free metanephrine, free normetanephrine and free 3-methoxytyramine are of clinical importance, primarily as an aid to diagnosis and monitoring of suspected pheochromocytoma and paraganglioma.</p> <p>Moreover, the assay is intended to be used for patients in whom the urinary levels of free normetanephrine and free 3-methoxytyramine are of clinical importance, as an aid to diagnosis and monitoring of suspected neuroblastoma.</p>
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	The assay is also intended to be used for patients in whom the urinary levels of serotonin are of clinical importance, primarily as an adjunct investigation in suspected carcinoid cases.		
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rules 3h		
GMDN Code	63892 "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"		
Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	Identification No.	2797
	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) IVDR 838647		
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, April 22 nd , 2026 Michael Meier, Managing Director		 Gräfelfing, April 22 nd , 2026 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	April 21 st , 2031	Version: 1.0	