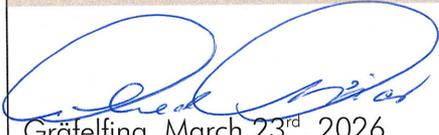


EU-Declaration of Conformity

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: 4250317810005K		
81000	LC-MS/MS Reagent Kit MassChrom [®] Free Metanephrines in plasma Including 96 SPE Well Plates	W01010499
81000/C	LC-MS/MS Reagent Kit MassChrom [®] Free Metanephrines in plasma Including Sample Clean Up Columns	W01010499
81001	Mobile Phase A	W01019099
81002	Mobile Phase B	W01019099
81003	Dilution Buffer	W01019099
81004	Internal Standard Mix	W0101050399
81005	Wash Buffer 1	W01019099
81006	Wash Buffer 2	W01019099
81007	Elution Buffer	W01019099
81009	Rinsing Solution	W01019099
81015	Tuning Mix, Analytes and Internal Standards	W0101050399
81055	Sample Clean Up Columns MassChrom [®] Free Metanephrines in plasma	W01019099
81056	Waste Plates MassChrom [®] Free Metanephrines in plasma	W01019099
81057	96 SPE Well Plate MassChrom [®] Free Metanephrines in plasma	W01019099
81058	Collection Plates MassChrom [®] Free Metanephrines in plasma	W01019099
81059	Pierceable Adhesive Seals, for 96 well plates MassChrom [®] Free Metanephrines in plasma	W01019099
81100	Analytical Column (equilibrated, with test chromatogram)	W01019099
81039	6PLUS1 [®] Multilevel Plasma Calibrator Set MassChrom [®] Free Metanephrines in plasma	W0101050301
0384	MassCheck [®] Free Metanephrines Plasma Control Level I	W0101050299
0385	MassCheck [®] Free Metanephrines Plasma Control Level II	W0101050299
0386	MassCheck [®] Free Metanephrines Plasma Control Level III	W0101050299

Device Intended Purpose	<p>The manual reagent test kit "MassChrom[®] Free Metanephrines in plasma" is an in vitro diagnostic medical product designed for professional users in clinical laboratories to quantitatively determine free metanephrine, free normetanephrine and free 3-methoxytyramine in human plasma samples through liquid chromatography with tandem mass spectrometry (LC-MS/MS). The test kit is intended to be used for patients in whom the plasma levels of free metanephrine, free normetanephrine and free 3-methoxytyramine are of clinical importance, primarily as an aid to diagnosis and monitoring of suspected pheochromocytoma or paraganglioma.</p> <p>Furthermore, the kit is intended to be used for patients in whom the plasma levels of free 3-methoxytyramine, or free 3-methoxytyramine in combination with free normetanephrine, are of clinical importance as an aid to diagnosis and monitoring of suspected neuroblastoma.</p>		
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3 (h)		
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	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	<p>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).</p> <p>Following Common Specifications were considered as part of determining device conformity with the IVDR:</p> <p>Not applicable as no Common Specifications exist for the concerned device.</p>		
Additional information	n/a		
This EU declaration of conformity is issued by			
 Gräfelfing, March 23 rd , 2026 Michael Meier, Managing Director		 Gräfelfing, March 23 rd , 2026 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	March 22 nd , 2031	Version: 2.0	