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

Chromsystems Instruments & Chemicals GmbH
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Managementsystem zertifiziert nach: ISO 9001, ISO 13485 (including MDSAP)

Device Intended Purpose	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. 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.		
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	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, March 01st, 2024 Michael Meier, Managing Director	Gräfelfing, March 01st, 2024 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	July 20th, 2027	Version: 1.1	

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