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: 42503172020B4N		
2020-B	HPLC Reagent Kit Metanephrines in urine	W01010499
2020-BK	HPLC Basic Kit Metanephrines in urine	W01010499
2020/A1	HPLC Reagent Kit Metanephrines in urine Preparation with the Gilson® ASPEC®	W01010499
2020/A5	HPLC Reagent Kit Metanephrines in urine Preparation with the Gilson® ASPEC®	W01010499
2020/A9	HPLC Reagent Kit Metanephrines in urine Preparation with the Gilson® ASPEC®	W01010499
2021	Mobile Phase	W01019099
2022	Mobile Phase	W01019099
2033	Analytes Mix	W0101050399
2009	Urine Calibration Standard	W0101050302
2009/T	Urine Calibration Standard	W0101050302
2024	Internal Standard	W0101050399
2024/A1	Internal Standard	W0101050399
2044/HR	Internal Standard High Resolution	W0101050399
2025	Neutralisation Buffer	W01019099
2025/A1	Neutralisation Buffer	W01019099
2025/A5	Neutralisation Buffer	W01019099
2026	Wash Buffer	W01019099
2026/A1	Wash Buffer	W01019099
2026/A5	Wash Buffer	W01019099
2027	Elution Buffer	W01019099
2028	Sample Clean Up Columns	W01019099
2028/A	Sample Clean Up Columns with DEC caps	W01019099
2120	HPLC Column	W01019099
Basic UDI-DI: 4250317102040502B		
0040	Endocrine Urine Control, Normal Range	W0101050207
0050	Endocrine Urine Control, Pathological Range	W0101050207

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Device Intended Purpose	The Chromsystems assay "Metanephrines in urine" is an in vitro diagnostic medical device designed for professional users in clinical laboratories for the quantitative determination of total (sum of free and conjugated metabolites) normetanephrine, metanephrine and 3-methoxytyramine in human urine samples. Sample preparation is carried out manually or semi-automated on ASPEC® (simple liquid handling system), and analytic separation is done via high performance liquid chromatography with electrochemical detection (HPLC-ECD). The assay is intended to be used for patients in whom the urinary levels of total normetanephrine, total metanephrine 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 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	63823 "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography"		
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, December 18th, 2024 Michael Meier, Managing Director	Gräfelfing, December 18th, 2024 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	December 17th, 2029	Version: 1.0	

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)