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: 42503171000C43		
1000-C	HPLC Reagent Kit VMA, HVA, 5-HIAA in urine	W01010499
1000-BK	HPLC Basic Kit VMA, HVA, 5-HIAA in urine	W01010499
1000/B/A1	HPLC Reagent Kit VMA, HVA, 5-HIAA in urine Preparation with the Gilson® ASPEC®	W01010499
1000/B/A5	HPLC Reagent Kit VMA, HVA, 5-HIAA in urine Preparation with the Gilson® ASPEC®	W01010499
1000/B/A9	HPLC Reagent Kit VMA, HVA, 5-HIAA in urine Preparation with the Gilson® ASPEC®	W01010499
1011	Mobile Phase	W01019099
1012	Mobile Phase	W01019099
1033	Analytes Mix	W0101050399
1009	Urine Calibration Standard	W0101050302
1009/T	Urine Calibration Standard	W0101050302
1004/B	Internal Standard VMA, HVA	W0101050399
1044/B/A1	Internal Standard VMA, HVA	W0101050399
1044/B/A5	Internal Standard VMA, HVA	W0101050399
1044/B/A9	Internal Standard VMA, HVA	W0101050399
51303/B	Internal Standard 5-HIAA	W0101050399
1005	Wash Buffer I	W01019099
1005/A5	Wash Buffer I	W01019099
1006	Wash Buffer II	W01019099
1006/A	Wash Buffer II	W01019099
1006/A5	Wash Buffer II	W01019099
1077	Elution Buffer	W01019099
1077/A5	Elution Buffer	W01019099
1013	Finisher	W01019099
1013/A5	Finisher	W01019099
1008	Sample Clean Up Columns	W01019099
1008/A	Sample Clean Up Columns with DEC caps	W01019099
1100/B	HPLC Column	W01019099

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

Basic UDI-DI: 42503171020405O2B		
0040	Endocrine Urine Control, Normal Range	W0101050207
0050	Endocrine Urine Control, Pathological Range	W0101050207

Device Intended Purpose	The Chromsystems assay "VMA, HVA, 5-HIAA in urine" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of vanillylmandelic acid (VMA), homovanillic acid (HVA), and 5-hydroxyindoleacetic acid (5-HIAA) 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 both vanillylmandelic acid (VMA) and homovanillic acid (HVA) are of clinical importance, primarily as an aid to diagnosis and monitoring of suspected neuroblastoma. Furthermore, the assay is intended to be used for patients in whom the urinary levels of 5-hydroxyindoleacetic acid (5-HIAA) are of clinical importance, primarily as an aid to diagnosis and monitoring of suspected carcinoids and serotonin-secreting neuroendocrine tumours.		
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3h		
GMDN Code	60606 "HVA/VMA/5HIAA 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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