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: 4250317440004U		
44000	HPLC Reagent Kit **Porphyrins in urine**	W01010499
44001	Mobile Phase A	W01019099
44002	Mobile Phase B	W01019099
44003	Urine Calibration Standard	W0101050302
44004	Internal Standard	W0101050399
44005	Stabilisation Reagent	W01019099
44006	Priming Solution	W01019099
0144	Urine Control Bi-Level (I + II)	W0101050207
0145	Urine Control Level I	W0101050207
0146	Urine Control Level II	W0101050207
44100	HPLC Column (equilibrated, with test chromatogram)	W01019099
18044	Precolumn Cartridge 4/10	W01019099

Device Intended Purpose	The Chromsystems reagent kit "Porphyrins in urine" is an *in vitro* diagnostic medical device for professional use in clinical laboratories for the quantitative detection of uroporphyrin, heptacarboxyporphyrin, hexacarboxyporphyrin, pentacarboxyporphyrin, coproporphyrin I and coproporphyrin III in human urine samples. Sample preparation is carried out manually, and analytic separation is done via high performance liquid chromatography (HPLC). The kit is intended to be used for patients in whom the urinary levels of uroporphyrin, heptacarboxyporphyrin, hexacarboxyporphyrin, pentacarboxyporphyrin, coproporphyrin I and coproporphyrin III are of clinical importance, primarily as an aid to diagnosis of suspected *Acute Intermittend Porphyria*, *Porphyria Variegata*, *Aminolevulinic Acid Dehydratase Deficiency Porphyria*, *Hereditary Coproporphyria*, *Porphyria Cutanea Tarda* or *Congenital Erythropoietic Porphyria* and/or for their differential diagnosis. The kit is also intended to be used as an aid to diagnosis of *lead poisoning* in patients in whom the urinary levels of above listed analytes are of clinical importance after suspected lead exposure (lead itself cannot be detected with this kit).

Chromsystems Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com

	Besides, the kit is also intended to be used as an aid to diagnosis of the *Dubin-Johnson Syndrome* in patients in whom the urinary levels of coproporphyrin I and coproporphyrin III are of clinical interest.		
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
GMDN Code	53539, term "Total porphyrin (coproporphyrin/uroporphyrin) 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, 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

Chromsystems Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com