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: 4250317929167Z		
92916	*MassTox*® TDM Series A PARAMETER Set Mycophenolic Acid in serum/plasma	W01010499
46029	3PLUS1® Multilevel Plasma Calibrator Set *MassTox*® Mycophenolic Acid/Glucuronide	W0101050301
46039	6PLUS1® Multilevel Plasma Calibrator Set *MassTox*® Mycophenolic Acid/Glucuronide	W0101050301
46039/XL	6PLUS1® Multilevel Plasma Calibrator Set *MassTox*® Mycophenolic Acid/Glucuronide	W0101050301
0234	*MassCheck*® Mycophenolic Acid/Glucuronide Plasma Control Bi-Level (I + II)	W0101050299
0235	*MassCheck*® Mycophenolic Acid/Glucuronide Plasma Control Level I	W0101050299
0236	*MassCheck*® Mycophenolic Acid/Glucuronide Plasma Control Level II	W0101050299
92246	Internal Standard Set *MassTox*® Mycophenolic Acid/Glucuronide	W0101050399
92019	Tuning Mix Analytes and Internal Standard	W0101050399

Basic UDI-DI: 4250317921116F		
92111/200	*MassTox*® TDM Series A BASIC Kit, Kit content for 200 analyses	W01010499
92111/1000	*MassTox*® TDM Series A BASIC Kit, Kit content for 1000 analyses	W01010499
92111/1000/F	*MassTox*® TDM Series A BASIC Kit for sample preparation with 96 Well Filter Plates, Kit content for 1000 analyses	W01010499
92001	Mobile Phase 1	W01019099
92002	Mobile Phase 2	W01019099
92003	Precipitation Reagent	W01019099
92005	Extraction Buffer	W01019099
92007	Dilution Buffer 1	W01019099
92008	Dilution Buffer 2	W01019099
92009	Rinsing Solution	W01019099
92012	Precipitation Reagent for 96 well filter plates	W01019099

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92057	96 Well Filter Plates	W01019099
92058	96 Well Collection Plates	W01019099
92059	Pierceable Adhesive Seals	W01019099

92110	*MassTox*® TDM MasterColumn® Series A Analytical column	W01019099

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Device Intended Purpose	The Chromsystems "*MassTox*® TDM Series A PARAMETER Set Mycophenolic Acid in serum/plasma" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of mycophenolic acid and its metabolite mycophenolic acid glucuronide in human serum or plasma samples via liquid chromatography mass spectrometry (LC-MS/MS). Manual sample preparation and chromatographic separation are carried out with the Chromsystems "*MassTox*® TDM Series A BASIC Kit" (order no. 92111), which provides the required reagents and buffers, and with the "*MassTox*® TDM MasterColumn® Series A" (order no. 92110). The Chromsystems "*MassTox*® TDM Series A PARAMETER Set Mycophenolic Acid in serum/plasma" is intended as a therapeutic drug monitoring test, medically indicated for patients treated with mycophenolate mofetil or mycophenolate sodium.		
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3j		
GMDN Code	61998: Mycophenolate therapeutic drug monitoring 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 28th, 2024 Michael Meier, Managing Director	Gräfelfing, March 28th, 2024 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	July, 20th 2027	Version: 1.0	

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