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: 4250317930006C		
93000	**LC-MS/MS Reagent Kit *MassTox*® Immunosuppressants in whole blood** Kit content for 400 analyses	W01010499
93000/1200	**LC-MS/MS reagent kit *MassTox*® Immunosuppressants in whole blood** Kit content for 1200 analyses	W01010499
93900/400	**LC-MS/MS Reagent Kit *MassTox*® Immunosuppressants in whole blood ONE*MINUTE* Test** Kit content for 400 analyses	W01010499
93900/1200	**LC-MS/MS Reagent Kit *MassTox*® Immunosuppressants in whole blood ONE*MINUTE* Test** Kit content for 1200 analyses	W01010499
93900/1200/DWP	**LC-MS/MS Reagent Kit *MassTox*® Immunosuppressants in whole blood ONE*MINUTE* Test** For sample preparation with 96 deep well extraction plates. Kit content for 1200 analyses	W01010499
Products individually available for reagent kit 93000		
93001	Mobile Phase A	W01019099
93002	Mobile Phase B	W01019099
93003	Precipitation Reagent	W01019099
93005	Extraction Buffer	W01019099
93009	Rinsing Solution	W01019099
93015	Tuning Mix, Analytes and Internal Standards	W0101050399
93046	Internal Standard Set, consisting of: - Internal Standard Mix - Reconstitution Buffer	W0101050399
93100	Analytical column (equilibrated with test chromatogram)	W01019099
93110	Trap column (equilibrated with test chromatogram)	W01019099

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www.chromsystems.com
Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

Products individually available for reagent kit 93900		
93911	Mobile Phase A	W01019099
93922	Mobile Phase B	W01019099
93003	Precipitation Reagent	W01019099
93005	Extraction Buffer	W01019099
93909	Rinsing Solution	W01019099
93915	Tuning Mix, Analytes and Internal Standards	W0101050399
93946	Internal Standard Set, consisting of: - Internal Standard Mix - Reconstitution Buffer	W0101050399
93100	Analytical Column, equilibrated with test chromatogram	W01019099
93122	Trap Column, equilibrated with test chromatogram	W01019099
93956	96 Deep Well Extraction Plates	W01019099
93058	Collection Plates	W01019099
93059	Pierceable Adhesive Seals for 96 Well Plates	W01019099
93060	Pierceable Heat Seals for 96 Well Plates	W01019099
Multilevel calibrators and MassCheck® controls		
28039/XL	**6PLUS1**® Multilevel Whole Blood Calibrator Set	W0101050301
28039	**6PLUS1**® Multilevel Whole Blood Calibrator Set	W0101050301
0081	***MassCheck***® Immunosuppressants Whole Blood Control Four-Level (I + II + III + IV)	W0101050299
0082	***MassCheck***® Immunosuppressants Whole Blood Control Level I	W0101050299
0083	***MassCheck***® Immunosuppressants Whole Blood Control Level II	W0101050299
0084	***MassCheck***® Immunosuppressants Whole Blood Control Level III	W0101050299
0085	***MassCheck***® Immunosuppressants Whole Blood Control Level IV	W0101050299
0089	***MassCheck***® Immunosuppressants Whole Blood Blank Control	W0101050299

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Device Intended Purpose	Order nos.: 93000, 93000/1200: The "***MassTox***® Immunosuppressants in whole blood" reagent kit is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of cyclosporin A, everolimus, sirolimus (rapamycin) and tacrolimus (FK-506) in human EDTA whole blood samples. Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS). The kit is intended as a therapeutic drug monitoring test for patients treated with one or several immunosuppressants named above. Order nos.: 93900/400, 93900/1200, 93900/DWP: The "***MassTox***® Immunosuppressants in whole blood ONE*MINUTE* Test" reagent kit is an in vitro diagnostic medical product designed for professional users in clinical laboratories for the quantitative detection of cyclosporin A, everolimus, sirolimus (rapamycin) and tacrolimus (FK-506) in human EDTA whole blood samples. Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS). The kit is intended as a therapeutic drug monitoring test for patients treated with one or several immunosuppressants named above.
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3 j
GMDN Code	62017: Multiple immunosuppressant 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		

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, October 02nd, 2023
Michael Meier, Managing Director

Gräfelfing, October 02nd, 2023
Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:	July 20th, 2027	Version: 1.0

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