

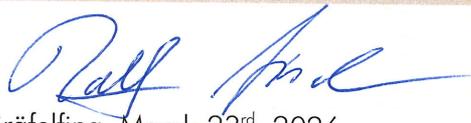
EU-Declaration of Conformity

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 ONEMINUTE Test Kit content for 400 analyses	W01010499
93900/1200	LC-MS/MS Reagent Kit MassTox® Immunosuppressants in whole blood ONEMINUTE Test Kit content for 1200 analyses	W01010499
93900/1200/DWP	LC-MS/MS Reagent Kit MassTox® Immunosuppressants in whole blood ONEMINUTE 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
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

93925	Tuning Mix, Analytes and Internal Standards	W0101050399
93936	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

Device Intended Purpose	<p>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 determination 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.</p> <p>Order nos.: 93900/400, 93900/1200, 93900/DWP: The "MassTox® Immunosuppressants in whole blood ONEMINUTE Test" reagent kit is an in vitro diagnostic medical product designed for professional users in clinical laboratories for the quantitative determination of cyclosporin A, everolimus, sirolimus (rapamycin) and tacrolimus (FK-506) in human EDTA whole blood samples.</p>
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	<p>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.</p>		
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	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	Identification No.	2797
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) IVDR 838647		
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 23 rd , 2026 Michael Meier, Managing Director		 Gräfelfing, March 23 rd , 2026 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	March 22 nd , 2031	Version: 2.0	