

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: 92922/XT: 425031792922XTR6		
92922/XT	MassTox [®] TDM Series A PARAMETER Set Antimycotic Drugs/EXTENDED in serum/plasma	W01010499
92051/XT	3PLUS1 [®] Multilevel Plasma Calibrator Set MassTox [®] Antimycotic Drugs/EXTENDED	W0101050301
0252/XT	MassCheck [®] Antimycotic Drugs/EXTENDED Plasma Control Bi- Level (I + II)	W0101050299
0253/XT	MassCheck [®] Antimycotic Drugs/EXTENDED Plasma Control Level I	W0101050299
0254/XT	MassCheck [®] Antimycotic Drugs/EXTENDED Plasma Control Level II	W0101050299
92644/XT	Internal Standard Mix MassTox [®] Antimycotic Drugs/EXTENDED	W0101050399
92039/XT	Tuning Mix MassTox [®] Antimycotic Drugs/EXTENDED	W0101050399

Basic UDI-DI: 92111: 4250317921116F		
92111/200	MassTox [®] TDM BASIC Kit A, for 200 analyses	W01010499
92111/1000	MassTox [®] TDM BASIC Kit A, 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
92110	MassTox [®] TDM MasterColumn [®] Series A Analytical column (equilibrated, with test chromatogram)	W01019099

Device Intended Purpose	<p>The Chromsystems parameter set "MassTox® TDM Series A Antimycotic Drugs/EXTENDED in serum/plasma" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of anidulafungin, caspofungin, fluconazole, 5-flucytosine, isavuconazole, itraconazole, hydroxyitraconazole, ketoconazole, micafungin, posaconazole and voriconazole in human serum or plasma samples via liquid chromatography mass spectrometry (LC-MS/MS).</p> <p>Manual sample preparation and chromatographic separation is carried out with the Chromsystems "MassTox® TDM BASIC Kit A" (order no. 92111), which provides the required reagents and buffers, and with the "MassTox® TDM MasterColumn® Series A" (order no. 92110).</p> <p>The Chromsystems parameter set "MassTox® TDM Series A Antimycotic Drugs/EXTENDED in serum/plasma" is intended as a therapeutic drug monitoring test, medically indicated for patients treated with one or more of the antimycotic drugs listed above.</p>		
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
GMDN Code	64329, term "Multiple antifungal 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	