

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

Basic UDI-DI: 92111: 4250317921116F		
92111/200	<i>MassTox</i> [®] TDM BASIC Kit A, for 200 analyses	W01010499
92111/1000	<i>MassTox</i> [®] 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	<i>MassTox</i> [®] TDM MasterColumn [®] Series A Analytical column (equilibrated, with test chromatogram)	W01019099
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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	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	<p>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).</p> <p>Following Common Specifications were considered as part of determining device conformity with the IVDR:</p> <p>Not applicable as no Common Specifications exist for the concerned device.</p>	
Additional information	n/a	
This EU declaration of conformity is issued by		
Gräfelfing, August 1 st , 2022 _____, Managing Director	Gräfelfing, August 1 st , 2022 _____, PRRC	
EU declaration of conformity valid until	July 20 th , 2027	Version: 1.0