

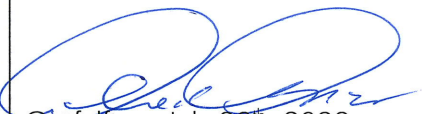
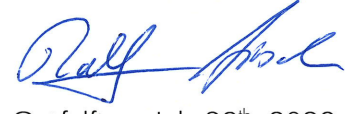
EU-Declaration of Conformity

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: 92912/XT: 425031792912XTQX		
92912/XT	MassTox [®] TDM Series A PARAMETER Set Neuroleptics 1/EXTENDED in serum/plasma	W01010499
92028/XT	3PLUS1 [®] Multilevel Plasma Calibrator Set MassTox [®] Neuroleptics 1/EXTENDED	W0101050301
0210/XT	MassCheck [®] Neuroleptics 1/EXTENDED Plasma Control Bi-Level (I + II)	W0101050299
0211/XT	MassCheck [®] Neuroleptics 1/EXTENDED Plasma Control Level I	W0101050299
0212/XT	MassCheck [®] Neuroleptics 1/EXTENDED Plasma Control Level II	W0101050299
92046/AN1/XT	Internal Standard Set - MassTox [®] Antidepressants 1/EXTENDED - MassTox [®] Neuroleptics 1/EXTENDED	W0101050399
92015/N1/XT	Tuning Mix MassTox [®] Neuroleptics 1/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
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Device Intended Purpose	<p>The Chromsystems parameter set "MassTox[®] TDM Series A Parameter Set Neuroleptics 1/EXTENDED in Serum/Plasma" is an <i>in vitro</i> diagnostic medical device for professional use in clinical laboratories for the quantitative determination of aripiprazole, dehydroaripiprazole, clozapine, desmethylclozapine, haloperidol, quetiapine, norquetiapine, risperidone and 9-OH-risperidone in human serum or plasma samples as well as olanzapine and N-desmethylolanzapine in human EDTA plasma samples via liquid chromatography mass spectrometry (LC-MS/MS). Manual sample preparation and chromatographic separation are 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). The Chromsystems parameter set "MassTox[®] TDM Series A Parameter Set Neuroleptics 1/EXTENDED in Serum/Plasma" is intended as a therapeutic drug monitoring test, medically indicated for patients treated with one or more of the neuroleptic drugs listed above.</p>		
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
GMDN Code	64333, term "Multiple antipsychotic 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: 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, July 28 th , 2023 Michael Meier, Managing Director		 Gräfelfing, July 28 th , 2023 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	July 20 th , 2027	Version: 1.0	