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	The Chromsystems "***MassTox***® TDM Series A PARAMETER Set Neuroleptics 1/EXTENDED in serum/plasma" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of aripiprazole, dehydroaripiprazole, clozapine, desmethylclozapine, haloperidol, olanzapine, N-desmethylolanzapine, quetiapine, norquetiapine, risperidone and 9-OH-risperidone in human serum or plasma samples via liquid chromatography mass spectrometry (LC-MS/MS). Manual sample preparation and chromatographic separation are carried out with the Chromsystems "***MassTox***® TDM Series A BASIC Kit" (order no. 92111), which provides the required reagents and buffers, and with the "***MassTox***® TDM MasterColumn® Series A" (order no. 92110). The Chromsystems "***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.		
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 Chapters I and III		
Certificates issued	EU Quality management System Certificate (IVDR) No. V12 057136 0015 Rev01		
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, November 17th, 2025 Michael Meier, Managing Director	Gräfelfing, November 17th, 2025 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	November 16th, 2030		Version: 1.2

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)