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: 425031792921XT2L2		
92921-XT2	*MassTox*® TDM Series A PARAMETER Set Antiepileptic Drugs XT2 in serum/plasma All-in-One Method	W01010499
92025-XT2	3PLUS1® Multilevel Plasma Calibrator Set *MassTox*® Antiepileptic Drugs XT2	W0101050301
0249-XT2	*MassCheck*® Antiepileptic Drugs XT2 Plasma Control Bi-Level (I+II)	W0101050299
0250-XT2	*MassCheck*® Antiepileptic Drugs XT2 Plasma Control Level I	W0101050299
0251-XT2	*MassCheck*® Antiepileptic Drugs XT2 Plasma Control Level II	W0101050299
92546-XT2	Internal Standard Mix *MassTox*® Antiepileptic Drugs XT2	W0101050399
92034-XT2	Tuning Mix 1 Analytes and Internal Standards	W0101050399
92035-XT2	Tuning Mix 2 Analytes and Internal Standards	W0101050399
92036-XT2	Tuning Mix 3 Analytes and Internal Standards	W0101050399
92037-XT2	Tuning Mix 4 Analytes and Internal Standards	W0101050399
92038-XT2	Tuning Mix 5 Analytes and Internal Standards	W0101050399

Basic UDI-DI: 4250317921116F		
92111/200	*MassTox*® TDM Series A BASIC Kit, Kit content for 200 analyses	W01010499
92111/1000	*MassTox*® TDM Series A BASIC Kit, Kit content 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

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92110	*MassTox*® TDM MasterColumn® Series A Analytical column	W01019099

Device Intended Purpose	The Chromsystems "*MassTox*® TDM Series A PARAMETER Set Antiepileptic Drugs XT2 in serum/plasma All-in-One Method" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of brivaracetam, carbamazepine, 10-OH-carbamazepine, carbamazepine-10,11-epoxide, cenobamate, N-desmethylmesuximide, ethosuximide, felbamate, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, perampanel, phenobarbital, phenylethylmalonamide (PEMA), phenytoin, pregabalin, primidone, rufinamide, stiripentol, sultiame, theophylline, tiagabine, topiramate, valproic acid, vigabatrin and zonisamide 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 Antiepileptic Drugs XT2 in serum/plasma All-in-One Method" is intended as a therapeutic drug monitoring test, medically indicated for patients treated with one or more of the antiepileptic drugs listed above and/or theophylline.		
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
GMDN Code	62443, term „Multiple anticonvulsant 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		

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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, June 12th, 2025 Michael Meier, Managing Director	Gräfelfing, June 12th, 2025 Dr. Ralf Fischer, PRRC
EU declaration of conformity valid until:	June, 11th, 2030 — Version: 1.0

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