

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

<p>Device Intended Purpose</p>	<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>		
<p>Risk Class</p>	<p>B, as per EU Regulation 2017/746, Annex VIII, Rule 6</p>		
<p>GMDN Code</p>	<p>64333, term "Multiple antipsychotic therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"</p>		
<p>Notified Body</p>	<p>BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands</p>	<p>Identification No.</p>	<p>2797</p>
<p>Conformity Assessment</p>	<p>Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX Chapters I and III</p>		
<p>Certificates issued</p>	<p>EU Quality management System Certificate (IVDR) IVDR 838647</p>		
<p>Declarations</p>			
<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>			
<p>Additional information</p>	<p>n/a</p>		
<p>This EU declaration of conformity is issued by</p>			
 Gräfelfing, March 23 rd , 2026 Michael Meier, Managing Director		 Gräfelfing, March 23 rd , 2026 Dr. Ralf Fischer, PRRC	
<p>EU declaration of conformity valid until:</p>	<p>March 22nd, 2031</p>	<p>Version: 2.0</p>	