# EU-Declaration of Conformity

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| Manufacturer | Chromsystems Instruments & Chemicals GmbH |
| Address | Am Haag 12<br>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<br>PARAMETER Set<br>Neuroleptics 1/*EXTENDED* in serum/plasma | W01010499 |
| 92028/XT | **3PLUS1**® Multilevel Plasma Calibrator Set<br>***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<br>- ***MassTox***® Antidepressants 1/EXTENDED<br>- ***MassTox***® Neuroleptics 1/EXTENDED | W0101050399 |
| 92015/N1/XT | Tuning Mix<br>***MassTox***® Neuroleptics 1/EXTENDED | W0101050399 |

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| 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 |

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| 92110 | ***MassTox***® TDM MasterColumn® Series A<br>Analytical column (equilibrated, with test chromatogram) | W01019099 |



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| Device Intended Purpose | The Chromsystems parameter set "**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, 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).<br>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).<br>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. | | |
| 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)" | | |
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| Notified Body | TÜV Süd Product Service GmbH<br>Ridlerstraße 65,<br>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 | | | |
| This EU declaration of conformity is issued under the sole responsibility of the manufacturer.<br>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 | | |
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| This EU declaration of conformity is issued by | | | |
| Gräfelfing, July 28th, 2023<br>Michael Meier, Managing Director | Gräfelfing, July 28th, 2023<br>Dr. Ralf Fischer, PRRC | | |
| EU declaration of conformity valid until: | July 20th, 2027 | Version: 1.0 | |



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