

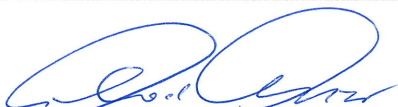

EU-Declaration of Conformity

| | |
|----------------------------------|---|
| 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: 92913/XT: 425031792913XTR4 | | |
| 92913/XT | MassTox ® TDM Series A PARAMETER Set Antidepressants 1/EXTENDED in serum/plasma | W01010499 |
| 92029/XT | 3PLUS1 ® Multilevel Plasma Calibrator Set MassTox ® Antidepressants 1/EXTENDED | W0101050301 |
| 0213/XT | MassCheck ® Antidepressants 1/EXTENDED Plasma Control Bi-Level (I + II) | W0101050299 |
| 0214/XT | MassCheck ® Antidepressants 1/EXTENDED Plasma Control Level I | W0101050299 |
| 0215/XT | MassCheck ® Antidepressants 1/EXTENDED Plasma Control Level II | W0101050299 |
| 92046/AN1/XT | Internal Standard Set - MassTox ® Antidepressants 1/EXTENDED - MassTox ® Neuroleptics 1/EXTENDED | W0101050399 |
| 92016/A1/XT | Tuning Mix MassTox ® Antidepressants 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 |
|-------|---|-----------|

| | | | |
|--|--|--|--------------|
| Device Intended Purpose | <p>The Chromsystems parameter set "MassTox[®] TDM Series A Antidepressants 1/<i>EXTENDED</i> in Serum/Plasma" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of citalopram (as sum of S- and R-citalopram), N-desmethylcitalopram, duloxetine, fluoxetine, desmethylfluoxetine, fluvoxamine, mirtazapine, N-desmethylmirtazapine, paroxetine, sertraline, N-desmethylsertraline, venlafaxine and O-desmethyl-venlafaxine in human serum or plasma samples via liquid chromatography mass spectrometry (LC-MS/MS).</p> <p>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).</p> <p>The Chromsystems parameter set "MassTox[®] TDM Series A Antidepressants 1/<i>EXTENDED</i> in Serum/Plasma" is intended as a therapeutic drug monitoring test, medically indicated for patients treated with one or more of the antidepressant 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 | | | |
| 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, 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 |