CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

# EC-Declaration of Conformity

according to directive 98/79 EC on in vitro diagnostic medical devices

We, as manufacturer

*Chromsystems Instruments & Chemicals GmbH*
*Am Haag 12*
*82166 Gräfelfing, Germany*

declare on our own responsibility, that herein after called in vitro diagnostic medical devices for the LC-MS/MS determination of:

GMDN code 61820, term "Tricyclic antidepressant therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)

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|---|---|
| EDMA Nomenclature term: | Other Central Nervous System TDM |
| EDMA Nomenclature code: | 12-08-02-90 |
| IVDD Classification: | *other product* |

Reagent Kit: 92919 - ***MassTox®*** TDM Series A PARAMETER-Set
Tricyclic Antidepressants TCA 1 in Serum/Plasma

Calibrator: 92032 - 3PLUS1® Multilevel Plasma Calibrator Set ***MassTox®***
Tricyclic Antidepressants TCA 1

Controls: 0243 - ***MassCheck®*** **Tricyclic Antidepressants TCA 1**
Plasma Control, Bi-Level (I + II)
0244 - ***MassCheck®*** **Tricyclic Antidepressants TCA 1**
Plasma Control, Level I
0245 - ***MassCheck®*** **Tricyclic Antidepressants TCA 1**
Plasma Control, Level II

Products:
92446 - Internal Standard Mix ***MassTox®*** Tricyclic Antidepressants
92022 - Tuning Mix ***MassTox®*** Tricyclic Antidepressants TCA 1

meet all applicable requirements of the directive 98/79/EC.

Conformity assessment procedure: Annex III of the directive 98/79/EC

Applied harmonized standards:
*EN ISO 13485, EN 13612, EN 13641, EN ISO 14971, EN 18113-1, EN 18113-2, EN 15223-1, EN 17511, EN 23640*

Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 3.0

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