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)"

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

Reagent Kit: 92920 - ***MassTox***® TDM Series A PARAMETER-Set
Tricyclic Antidepressants TCA 2 in Serum/Plasma

Calibrator: 92033 - 3PLUS1® Multilevel Plasma Calibrator Set ***MassTox***®
Tricyclic Antidepressants TCA 2

Controls: 0246 - ***MassCheck***® Tricyclic Antidepressants TCA 2
Plasma Control, Bi-Level (I + II)
0247 - ***MassCheck***® Tricyclic Antidepressants TCA 2
Plasma Control, Level I
0248 - ***MassCheck***® Tricyclic Antidepressants TCA 2
Plasma Control, Level II

Products:
92446 - Internal Standard Mix ***MassTox***® Tricyclic Antidepressants
92023 - Tuning Mix ***MassTox***® Tricyclic Antidepressants TCA 2

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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