

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: 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.

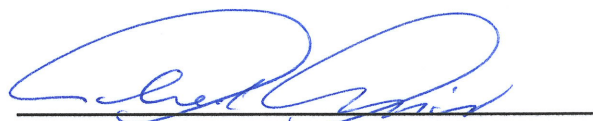
Conformity assessment procedure: Annex III of the directive 98/79/EC

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