

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 62515, term "Multiple 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: 92713/XT - **MassTox**® TDM Series A PARAMETER-Set
Antidepressants 1/EXTENDED in Serum/Plasma
For automated sample preparation on Hamilton MassSTAR

Calibrator: 92029/XT - 3PLUS1® Multilevel Plasma Calibrator Set **MassTox**®
Antidepressants 1/EXTENDED

Controls: 0213/XT - **MassCheck**® Antidepressants 1/EXTENDED Plasma Control,
Bi-Level (I + II)
0214/XT - **MassCheck**® Antidepressants 1/EXTENDED
Plasma Control, Level I
0215/XT - **MassCheck**® Antidepressants 1/EXTENDED
Plasma Control, Level II

Products:
92046/AN1/XT - Internal Standard Set **MassTox**®
Antidepressants 1/EXTENDED **MassTox**® Neuroleptics 1/EXTENDED
92016/A1/XT - Tuning Mix **MassTox**® Antidepressants 1/EXTENDED

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

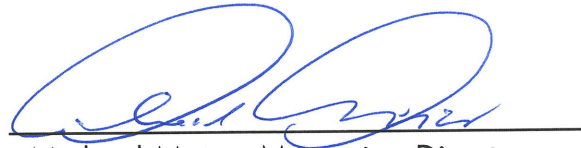
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 16th, 2022



Michael Meier, Managing Director