

## 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**<sup>®</sup> TDM Series A PARAMETER-Set  
Tricyclic Antidepressants TCA 2 in Serum/Plasma

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

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

Products:

92446 - Internal Standard Mix **MassTox**<sup>®</sup> Tricyclic Antidepressants  
92023 - Tuning Mix **MassTox**<sup>®</sup> Tricyclic Antidepressants TCA 2

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

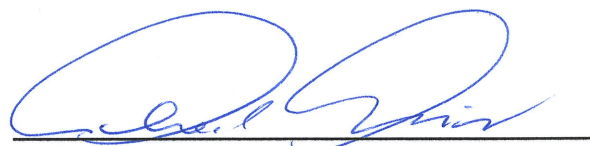
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 02<sup>nd</sup>, 2022



Michael Meier, Managing Director