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 64333, term "Multiple antipsychotic 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: **92712/XT - *MassTox*® TDM Series A PARAMETER-Set Neuroleptics 1/EXTENDED in Serum/Plasma For automated sample preparation on Hamilton MassSTAR**

Calibrator: **92028/XT - 3PLUS1® Multilevel Plasma Calibrator Set *MassTox*® Neuroleptics 1/EXTENDED**

Controls:
0210/XT - *MassCheck*® Neuroleptics 1/EXTENDED Plasma Control, Bi-Level (I + II)
0211/XT - *MassCheck*® Neuroleptics 1/EXTENDED Plasma Control, Level I
0212/XT - *MassCheck*® Neuroleptics 1/EXTENDED Plasma Control, Level II

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

92015/N1/XT - Tuning Mix *MassTox*® Neuroleptics 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

EC declaration valid until May 26th, 2027

Vers. 1.0