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 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

EC declaration valid until May 26th, 2027

Vers. 1.0

Chromsystems
Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com
Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

CHROMSYSTEMS
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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

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