

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: **92715/XT – MassTox® TDM Series A PARAMETER Set
Antidepressants 2/Psychostimulants/EXTENDED in serum/plasma
For automated sample preparation on Hamilton MassSTAR**

Calibrator: **92027/XT – 3PLUS1® Multilevel Plasma Calibrator Set
MassTox® Antidepressants 2/Psychostimulants/EXTENDED**

Controls: **0230/XT – MassCheck® Antidepressants 2/ Psychostimulants/EXTENDED
Plasma Control, Bi-Level (I + II)
0231/XT – MassCheck® Antidepressants 2/ Psychostimulants/EXTENDED
Plasma Control, Level I
0232/XT – MassCheck® Antidepressants 2/ Psychostimulants/EXTENDED
Plasma Control, Level II**

Products: **92146/XT - Internal Standard Mix
92018/XT - Tuning Mix MassTox®
Antidepressants 2/Psychostimulants/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