

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 61819, term "Benzodiazepine group 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: 92918 - **MassTox**® TDM Series A PARAMETER-Set
Benzodiazepines 2 in Serum/Plasma

Calibrator: 92031 - 3PLUS1® Multilevel Plasma Calibrator Set **MassTox**®
Benzodiazepines 2

Controls: 0240 - **MassCheck**® Benzodiazepines 2 Plasma Control, Bi-Level (I + II)
0241 - **MassCheck**® Benzodiazepines 2 Plasma Control, Level I
0242 - **MassCheck**® Benzodiazepines 2 Plasma Control, Level II

Products: 92346 - Internal Standard Mix **MassTox**® Benzodiazepines
92021 - Tuning Mix **MassTox**® Benzodiazepines 2

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

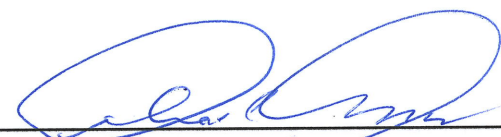
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 02nd, 2022



Michael Meier, Managing Director