

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: 64228, term "Multiple-therapy therapeutic drug monitoring IVD, 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: **92924 MassTox® TDM Series A PARAMETER-Set
Anti-HIV Drugs in serum/plasma**

Calibrator: **92053 6PLUS1® Multilevel Plasma Calibration Set
MassTox® Anti-HIV Drugs**

Controls: 0261 MassCheck® Anti-HIV Drugs Plasma Control, Bi-Level (I + II)
0262 MassCheck® Anti-HIV Drugs Plasma Control, Level I
0263 MassCheck® Anti-HIV Drugs Plasma Control, Level II

Products:

92844 Internal Standard Mix MassTox® Anti-HIV Drugs
92042 Tuning Mix MassTox® Anti-HIV Drugs

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

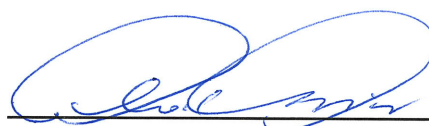
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 17th, 2022



Michael Meier, Managing Director