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: 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

EC declaration valid until May 26th, 2027

Vers. 4.0

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