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 63822, term "Multiple-therapy therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Other Central Nervous System TDM
EDMA Nomenclature code:	12-08-02-90
IVDD Classification:	*other product*

Reagent Kits:
92111/200 ***MassTox®*** TDM Series A Basic Kit, 200 analyses
92111/1000 ***MassTox®*** TDM Series A Basic Kit, 1000 analyses
92111/1000/F ***MassTox®*** TDM Series A Basic Kit, for automated sample preparation with 96 well filter plates, 1000 analyses

Products:

92001 - Mobile Phase 1
92002 - Mobile Phase 2
92003 - Precipitation Reagent
92005 - Extraction Buffer
92007 - Dilution Buffer 1
92008 - Dilution Buffer 2
92009 - Rinsing Solution
92110 - ***MassTox®*** TDM Master Column® Series A
92012 - Precipitation Reagent for automated sample preparation
92057 - 96 Well filter plates
92058 - 96 Well collection plates
92059 - Pierceable adhesive seals, for 96 well plates

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. 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

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

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