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 Kit: **92711 *MassTox*® TDM Series A Basic Kit for automated sample preparation on Hamilton MassSTAR**

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
92056 - 96 Deep Well Plates
92059 - Pierceable Adhesive Seals for 96 well plates
92060 - Pierceable Heat Seals for 96 Well Plates
CS235905 - High Vol. CO-RE tips, with filter, 1000 µL
CS235903 - Standard Vol. CO-RE tips, with filter, 300 µL

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

EC declaration valid until May 26th, 2027

Vers. 1.0

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Notified body: –

Gräfelfing, May 16th, 2022

Michael Meier, Managing Director

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