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 64329, term "Multiple antifungal therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term: Other Other Clinical Chemistry Reagents
EDMA Nomenclature code: 11-90-01-90-00
IVDD Classification: other product

Reagent Kit: 92722/XT - ***MassTox***® TDM Series A PARAMETER-Set
Antimycotic Drugs/EXTENDED in Serum/Plasma
For automated sample preparation on Hamilton MassSTAR

Calibrators: 92051/XT - 3PLUS1® Multilevel Plasma Calibrator Set ***MassTox***®
Antimycotic Drugs/EXTENDED

Controls: 0252/XT - ***MassCheck***® Antimycotic Drugs/EXTENDED
Plasma Control Bi-Level (I + II)

0253/XT - ***MassCheck***® Antimycotic Drugs/EXTENDED
Plasma Control Level I

0254/XT - ***MassCheck***® Antimycotic Drugs/EXTENDED
Plasma Control Level II

Products:

92644/XT - Internal Standard Set ***MassTox***® Antimycotic Drugs/EXTENDED

92039/XT - Tuning Mix ***MassTox***® Antimycotic Drugs/EXTENDED

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. 1.0

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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 16th, 2022

Michael Meier, Managing Director

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