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 Cardiovascular TDM
EDMA Nomenclature code:	12-08-01-90
IVDD Classification:	*other product*

Reagent Kit: 92923 - ***MassTox®*** TDM Series A PARAMETER-Set
Antiarrhythmic Drugs in Serum/Plasma

Calibrators: 92052 - 3PLUS1® Multilevel Plasma Calibrator Set ***MassTox®***
Antiarrhythmic Drugs
92054 - 6PLUS1® Multilevel Plasma Calibrator Set ***MassTox®***
Antiarrhythmic Drugs

Controls: 0264 - ***MassCheck®*** Antiarrhythmic Drugs
Plasma Control, Bi-Level (I + II)
0265 - ***MassCheck®*** Antiarrhythmic Drugs Plasma Control, Level I
0266 - ***MassCheck®*** Antiarrhythmic Drugs Plasma Control, Level II

Products:
92746 - Internal Standard Mix ***MassTox®*** Antiarrhythmic Drugs
92041 - Tuning Mix ***MassTox®*** Antiarrhythmic 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

EC declaration valid until May 26th, 2027

Vers. 3.0

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Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

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