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 62443, term "Multiple anticonvulsant therapeutic drug monitoring IVD, kit, 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: 92921 - ***MassTox***® TDM Series A PARAMETER-Set
Antiepileptic Drugs in serum/plasma

Calibrator: 92025 - 3PLUS1® Multilevel Plasma Calibrator Set
MassTox® Antiepileptic Drugs

Controls: 0249 - ***MassCheck***® Antiepileptic Drugs Plasma Control Bi-Level (I+II)
0250 - ***MassCheck***® Antiepileptic DrugsPlasma Control Level I
0251 - ***MassCheck***® Antiepileptic DrugsPlasma Control Level II

Products:

92546 - Internal Standard Mix ***MassTox***® Antiepileptic Drugs
92034 - Tuning Mix ***MassTox***® Antiepileptic Drugs 1
92035 - Tuning Mix ***MassTox***® Antiepileptic Drugs 2
92036 - Tuning Mix ***MassTox***® Antiepileptic Drugs 3
92037 - Tuning Mix ***MassTox***® Antiepileptic Drugs 4
92038 - Tuning Mix ***MassTox***® Antiepileptic Drugs 5
92085 – System Check Solution

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. 3.0

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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 02nd, 2022

Michael Meier, Managing Director

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