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 HPLC determination of:

GMDN Code: 61979, term "Multiple anticonvulsant therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA-Nomenclature term: Other Central Nervous System TDM
EDMA-Nomenclature code: 12-08-02-09-00
IVDD Classification: *other product*

Reagent Kit: **21000 Rufinamide, Felbamate, Lacosamide in serum/plasma**

Calibrator: **21003 Serum Calibration Standard**

Controls: **0065 Serum Control Bi-Level (I+II)**

Products:

21001	Mobile Phase
21002	Mobile Phase (10x)
22004	Internal Standard
22003	Precipitation Reagent
22006	Stabilisation Buffer
18022/FHR	Precolumn Cartridge 4/10
22100/F	HPLC Column, FAST ELUTION

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

Notified body: –

Gräfelfing, May 16th, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 3.0

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