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: **23000/F Antiepileptic Drugs in serum/plasma, FAST ELUTION**
23000/HR Antiepileptic Drugs in serum/plasma, HIGH RESOLUTION

Calibrator: **22005 Serum Calibration Standard**

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

Products:

21001/F	Mobile Phase
21001/HR	Mobile Phase
23004	Internal Standard
23006	Equilibration Buffer
23007	Wash Buffer
23008	Elution Buffer
23009	Sample Clean Up Columns with DEC caps
18022/FHR	Precolumn Cartridge 4/10
22100/F	HPLC Column, FAST ELUTION
22100/HR	HPLC Column, HIGH RESOLUTION

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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CHROMSYSTEMS
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Notified body: –

Gräfelfing, May 16th, 2022

Michael Meier, Managing Director

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)