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:	12-08-02-90-00
IVDD Classification:	*other product*

Reagent Kit:
22000/F - Antiepileptic Drugs in Serum/Plasma – FAST ELUTION
22000/HR - Antiepileptic Drugs in Serum/Plasma – HIGH RESOLUTION

Calibrators:
22005 - Serum Calibration Standard
22005/HR - Serum Calibration Standard HIGH RESOLUTION
28005 - Serum Calibration Standard
29004 - Serum Calibration Standard

Controls:
0060 - Serum Control, Level I
0160 - Serum Control, Level I
0070 - Serum Control, Level II
0170 - Serum Control, Level II
0080 - Serum Control, Level III
0180 - Serum Control, Level III
0166 - Serum Control, Bi-Level (I + II)
0188 - Serum Control, Tri-Level (I + II+ III)
0063 - Serum Control, Bi-Level (I + II)
0063/1 - Serum Control, Level I
0063/2 - Serum Control, Level II
0064 - Serum Control, Bi-Level (I + II)
0064/1 - Serum Control, Level I
0064/2 - Serum Control, Level II

Products:
22001/F - Mobile Phase FAST ELUTION

EC declaration valid until May 26th, 2027

Vers. 5.0

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22001/HR - Mobile Phase HIGH RESOLUTION
22003 - Precipitation Reagent
22004 - Internal Standard
22006 - Stabilisation Reagent
22100/F - HPLC column FAST ELUTION
22100/HR - HPLC column HIGH RESOLUTION
23004 – Internal Standard
23004/A5 – Internal Standard
23004/A9 – Internal Standard
23006 - Equilibration Buffer
23006/A5 - Equilibration Buffer
23007 - Wash Buffer
23007/A9 - Wash Buffer
23008 - Elution Buffer
23008/A5 - Elution Buffer
18022/F/HR - Precolumn Cartridge 4/10

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 02nd, 2022

Michael Meier, Managing Director

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