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: 55671, term "Levetiracetam 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: **24000 Levetiracetam (Keppra®) in serum/plasma**
Calibrator: **24003 Serum Calibration Standard**
Controls: 0086 Serum Control Bi-Level (I+II)
0087 Serum Control Level I
0088 Serum Control Level II

Products:

24001	Mobile Phase
24002	Mobile Phase (10x)
24001/HR	Mobile Phase HIGH RESOLUTION
24004	Internal Standard
24005	Equilibration Buffer 1
24006	Equilibration Buffer 2
24007	Wash Buffer 1
24008	Wash Buffer 2
24010	Elution Buffer
24008	Sample Clean Up Columns
18024	Precolumn Cartridge 4/10
24100	HPLC Column
24100/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

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 16th, 2022

Michael Meier, Managing Director

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