

## 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:

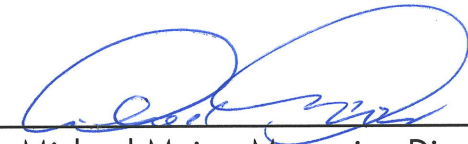
EN ISO 13485, EN 13612, EN 13641, EN ISO 14971, EN 18113-1, EN 18113-2,  
EN 15223-1, EN 17511, EN 23640

EC declaration valid until May 26<sup>th</sup>, 2027

Vers. 3.0

Notified body: -

Gräfelfing, May 16<sup>th</sup>, 2022



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Michael Meier, Managing Director

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