

## 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 LC-MS/MS determination of:

GMDN code 62443, term "Multiple anticonvulsant therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term: Other Central Nervous System TDM

EDMA Nomenclature code: 12-08-02-90

IVDD Classification: other product

Reagent Kit: 92921/XT - **MassTox**<sup>®</sup> TDM Series A PARAMETER-Set  
Antiepileptic Drugs/EXTENDED in serum/plasma

Calibrator: 92025/XT - 3PLUS1<sup>®</sup> Multilevel Plasma Calibrator Set  
**MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED

Controls: 0249/XT - **MassCheck**<sup>®</sup> Antiepileptic Drugs/EXTENDED Plasma Control Bi-Level  
(I+II)

0250/XT - **MassCheck**<sup>®</sup> Antiepileptic Drugs/EXTENDED Plasma Control Level I

0251/XT - **MassCheck**<sup>®</sup> Antiepileptic Drugs/EXTENDED Plasma Control Level II

Products:

92546/XT - Internal Standard Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED

92034/XT - Tuning Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED 1

92035/XT - Tuning Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED 2

92036/XT - Tuning Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED 3

92037/XT - Tuning Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED 4

92038/XT - Tuning Mix **MassTox**<sup>®</sup> Antiepileptic Drugs/EXTENDED 5

meet all applicable requirements of the directive 98/79/EC.

Conformity assessment procedure: Annex III of the directive 98/79/EC

# CHROMSYSTEMS

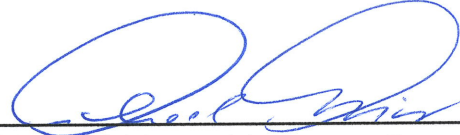
DIAGNOSTICS BY HPLC & LC-MS/MS

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 02<sup>nd</sup>, 2022



Michael Meier, Managing Director

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

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

Vers. 4.0

