

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 - **MassTox**[®] TDM Series A PARAMETER-Set
Antiepileptic Drugs in serum/plasma

Calibrator: 92025 - 3PLUS1[®] Multilevel Plasma Calibrator Set
MassTox[®] Antiepileptic Drugs

Controls: 0249 - **MassCheck**[®] Antiepileptic Drugs Plasma Control Bi-Level (I+II)
0250 - **MassCheck**[®] Antiepileptic Drugs Plasma Control Level I
0251 - **MassCheck**[®] Antiepileptic Drugs Plasma Control Level II

Products:
92546 - Internal Standard Mix **MassTox**[®] Antiepileptic Drugs
92034 - Tuning Mix **MassTox**[®] Antiepileptic Drugs 1
92035 - Tuning Mix **MassTox**[®] Antiepileptic Drugs 2
92036 - Tuning Mix **MassTox**[®] Antiepileptic Drugs 3
92037 - Tuning Mix **MassTox**[®] Antiepileptic Drugs 4
92038 - Tuning Mix **MassTox**[®] Antiepileptic Drugs 5
92085 - System Check Solution

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

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

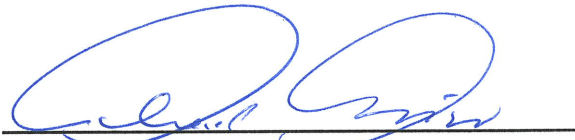
EC declaration valid until May 26th, 2027

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

