

## 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 63822, term "Multiple-therapy therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA Nomenclature term: Other Central Nervous System TDM

EDMA Nomenclature code: 12-08-02-90

IVDD Classification: other product

Reagent Kit: 92711 **MassTox**® TDM Series A Basic Kit  
for automated sample preparation on Hamilton MassSTAR

Products:

92001 - Mobile Phase 1  
92002 - Mobile Phase 2  
92003 - Precipitation Reagent  
92005 - Extraction Buffer  
92007 - Dilution Buffer 1  
92008 - Dilution Buffer 2  
92009 - Rinsing Solution  
92110 - **MassTox**® TDM Master Column® Series A  
92056 - 96 Deep Well Plates  
92059 - Pierceable Adhesive Seals for 96 well plates  
92060 - Pierceable Heat Seals for 96 Well Plates  
CS235905 - High Vol. CO-RE tips, with filter, 1000 µL  
CS235903 - Standard Vol. CO-RE tips, with filter, 300 µL

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

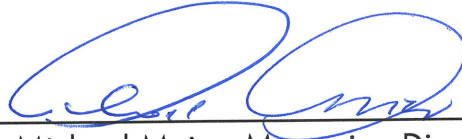
Vers. 1.0

# CHROMSYSTEMS

DIAGNOSTICS BY HPLC & LC-MS/MS

Notified body: -

Gräfelfing, May 16<sup>th</sup>, 2022



Michael Meier, Managing Director

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

Vers. 1.0