

## 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: 55458, term "Multiple drugs of abuse IVD, kit, liquid chromatography"

EDMA Nomenclature term: Other drugs of abuse  
EDMA Nomenclature code: 12-09-01-90-00  
IVDD Classification: general IVD, other product

Reagent Kits: **96000 - MassTox® Drugs of Abuse Testing in urine**  
**96000/WP - MassTox® Drugs of Abuse Testing in urine**

Calibrators: **96040 - 6PLUS1® Multilevel Urine Calibrator Set**  
**96033 - Urine Screening Standard Set**

Controls: **0410 - MassCheck® Drugs of Abuse Testing Urine Control Set Level I**  
**0420 - MassCheck® Drugs of Abuse Testing Urine Control Set Level II**  
**0430 - MassCheck® Drugs of Abuse Testing Urine Control Set Level III**  
**0470 - MassCheck® Drugs of Abuse Testing Urine Hydrolysis Control Set**

Products:  
**96001 - Mobile Phase A**  
**96002 - Mobile Phase B**  
**96005 - Precipitation Reagent**  
**96009 - Rinsing Solution**  
**96010 - Dilution Buffer**  
**96046 - Internal Standard Set**  
**96078 - Enzyme Solution Set**  
**96100 - Analytical Column**  
**96012 - System Check Solution**  
**96015 - Tuning Mix 1**

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

Vers. 3.0

**96016 - Tuning Mix 2**

**96017 - Tuning Mix 3**

**96057 - 96 Well Plates**

**96058 - Collection Plate**

**96059 - Pierceable Adhesive Seals, for 96 well plates**

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

Notified body: -

Gräfelfing, May 02<sup>nd</sup>, 2022



Michael Meier, Managing Director