

## 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 63892, term "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term: Other Individual and Specified Hormones

EDMA Nomenclature code: 12-06-90-90

IVDD Classification: other product

Reagent Kits: 80600/C - **MassChrom**® Biogenic Amines/Metabolites in urine  
Sample Prep Set - Catecholamines, free Metanephrines, Serotonin  
80600/96 - **MassChrom**® Biogenic Amines/Metabolites in urine  
Sample Prep Set - Catecholamines, free Metanephrines, Serotonin  
80600/480 - **MassChrom**® Biogenic Amines/Metabolites in urine  
Sample Prep Set - Catecholamines, free Metanephrines, Serotonin

Calibrator: 80639 - 6PLUS1® Multilevel Urine Calibrator Set

Controls: 0372 **MassCheck**® Catecholamines, free Metanephrines, Serotonin  
Urine Control Level I  
0373 **MassCheck**® Catecholamines, free Metanephrines, Serotonin  
Urine Control Level II

Chromatographic platform:  
80000 - **MassChrom**® Biogenic Amines/Metabolites in urine  
Chromatographic Platform, Starter Set  
80001 - Mobile Phase A  
80002 - Mobile Phase B  
80009 - Rinsing Solution  
80100 - Analytical column

Products:  
80603 - Adjustment Reagent  
80604 - Internal Standard Mix  
80604/5 - Internal Standard Mix  
80605 - Neutralisation Buffer

80675 - Neutralisation Buffer  
80606 - Wash Buffer 1  
80676 - Wash Buffer 1  
80607 - Wash Buffer 2  
80677 - Wash Buffer 2  
80608 - Elution Buffer  
80678 - Elution Buffer  
80609 - Dilution Buffer  
80679 - Dilution Buffer  
80055 - Sample Clean Up Columns  
80056 - Collection plates  
80057 - 96 SPE well plate  
80059 - Piercable adhesive seals for 96 well plates  
80610 - System Check Solution  
80615 - Tuning Mix

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