

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 Toxicology

EDMA Nomenclature code: 12-09-02-90-00

IVDD Classification: other product

Reagent Kits: 80700/C - **MassChrom**® Biogenic Amines/Metabolites in urine
Sample Prep Set - Total Metanephrines (free + conjugated)
80700/96 - **MassChrom**® Biogenic Amines/Metabolites in urine
Sample Prep Set - Total Metanephrines (free + conjugated)

Calibrator: 80739 - 6PLUS1® Multilevel Urine Calibrator Set

Controls: 0376 - **MassCheck**® Total Metanephrines Urine Control Level I
0377 - **MassCheck**® Total Metanephrines Urine Control Level I

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:
80703 -Hydrolysis Buffer
80704 - 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
80058 - Hydrolysis plates
80059 - Piercable adhesive seals for 96 well plates
80615 - Tuning Mix
80610 - System Check Solution

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 02nd, 2022

Michael Meier, Managing Director