CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

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 63929, term "HVA/VMA/5HIAA IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term:	Vanillylmandelic acid
EDMA Nomenclature code:	12-09-02-17
EDMA Classification:	*other product*

Reagent Kits:
80800 - ***MassChrom®*** Biogenic Amines/Metabolites in urine Sample Prep Set - VMA, HVA, 5-HIAA
80800/96 - ***MassChrom®*** Biogenic Amines/Metabolites in urine Sample Prep Set - VMA, HVA, 5-HIAA
80800/480 - ***MassChrom®*** Biogenic Amines/Metabolites in urine Sample Prep Set - VMA, HVA, 5-HIAA

Calibrator:
80839 – 6PLUS1® Multilevel Urine Calibrator Set

Controls:
0381 ***MassCheck®*** VMA, HVA, 5-HIAA Urine Control Level I
0382 ***MassCheck®*** VMA, HVA, 5-HIAA 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:
80804 - Internal Standard Mix
80804/5 - Internal Standard Mix
80805 - Neutralisation Buffer
80875 - Neutralisation Buffer
80056 - Collection plates
80059 - Piercable adhesive seals for 96 well plates

EC declaration valid until May 26th, 2026

Vers. 4.0

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80815 - Tuning Mix
80810 - System Check Solution
80200 - Analytical column

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

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