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 HPLC determination of:

GMDN code 60606, term "HVA/VMA/5HIAA IVD, kit, liquid chromatography"

EDMA Nomenclature term:	5-HIAA
EDMA Nomenclature code:	12-03-90-05-00
IVDD Classification:	*other product*

Reagent Kit: 51000 - 5-HIAA in Urine

Calibrator: 1009 - Urine Calibration Standard

Controls: 0040 – Endocrine Urine Control, Normal Range
0050 – Endocrine Urine Control, Pathological Range

Products:

51001 - Mobile Phase
51002 - Mobile Phase (10x)
51003 - Internal Standard
51005 - Precipitation Reagent
51100 - HPLC 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

EC declaration valid until May 26th, 2026

Vers. 3.0

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