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: 63823 "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Serotonin
EDMA Nomenclature code:	12-03-90-17-00
IVDD Classification:	*other product*

Reagent Kit: 4000 - Serotonin in Urine

Calibrator: 3003 - Calibration Standard
4009 - Urine Calibration Standard

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

Products:
3031 - Mobile Phase
3032 - Mobile Phase (10x)
4004 - Internal Standard
4055 - Neutralisation Reagent
4006 - Wash Buffer
4007 - Elution Buffer
4008 - Sample Clean Up Columns
4100 - 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:

EC declaration valid until May 26th, 2026

Vers. 5.0

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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. 5.0

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