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:	**3030 - Serotonin in Serum/Plasma/Whole Blood**
Calibrator:	**3009 - Plasma Calibration Standard**
Controls:	**0010 - Plasma Endocrine Control, Normal Range** **0020 - Plasma Endocrine Control, Pathological Range**

Products:

3031 - Mobile Phase
3032 - Mobile Phase (10x)
3033 - Calibration Standard
3034 - Internal Standard
3035 - Precipitation Reagent
3130 - 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. 5.0