

Addendum to

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, term "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography"

EDMA-Nomenclature term: Adrenaline / Noradrenaline / Dopamine

EDMA-Nomenclature code: 12-06-30-01-00

IVDD Classification: other product

Product name: **5000 – Catecholamines in Plasma**

Calibrators: **5003 – Calibration Standard**
5009 – Plasma Calibration Standard

Controls: **0010 – Plasma Endocrine Control, Normal Range**
0020 – Plasma Endocrine Control, Pathological Range

Components / Accessories for Catecholamines in Plasma

5001	Mobile Phase
5002	Mobile Phase (10x)
5001/K	Mobile Phase
5004	Internal Standard
5011	Extraction Buffer
5005	Wash Buffer
5006	Elution Buffer
5007	Sample Clean Up Column
5100	HPLC Column
5100/K	HPLC Column
5007/Vi	Plastic Vials for sample cleanup columns
5031	Mobile Phase L-DOPA, DHPG, DOPAC

EC declaration valid until December 31st, 2028

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HPLC Column L-DOPA, DHPG, DOPAC

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: –

Originally issued May 16nd, 2022 V6.0 is still valid until December 31st, 2028
according to regulation 2024/1860.

Gräfelfing, August 05th, 2026


Michael Meier, Managing Director