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
5130	HPLC Column L-DOPA, DHPG, DOPAC

EC declaration valid until May 26th, 2026

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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 16th, 2022

Michael Meier, Managing Director

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