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 64203, term "Malondialdehyde IVD, kit, liquid chromatography"

EDMA-Nomenclature term: Other Other Clinical Chemistry Reagents
EDMA-Nomenclature code: 11-90-01-90-00
IVDD Classification: *other product*

Product name: **67000 – Malondialdehyde in plasma/serum**

Calibrators: **67003 – Plasma Calibration Standard**

Controls: **0094 – Plasma Control Bi-Level (I + II)**
0095 – Plasma Control Level I
0096 – Plasma Control Level II

Components / Accessories for Catecholamines in Plasma

67001	Mobile Phase
67002	Mobile Phase (10x)
67005	Precipitation Reagent
67006	Derivatisation Reagent
67007	Neutralisation Reagent
67009	Derivatisation Vials
67100	HPLC Column
18067	Precolumn cartridge 4/10

meet all applicable requirements of the directive 98/79/EC.

Conformity assessment procedure: Annex III of the directive 98/79/EC

EC declaration valid until May 26th, 2027

Chromsystems Instruments & Chemicals GmbH
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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

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

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