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: 53748, term "Homocysteine IVD, kit, liquid chromatography"

EDMA Nomenclature term: Homocysteine
EDMA Nomenclature code: 12-13-01-09-00
IVDD Classification: *general IVD, other product*

Reagent Kit: **45000 - Homocysteine in plasma/serum**

Calibrator: **39004 - Plasma Calibration Standard**

Controls: **0071 - Plasma Control Bi-Level (I+II)**
0072 - Plasma Control Level I
0073 - Plasma Control Level II

Products:

39001 - Mobile Phase
39002 - Mobile Phase
45003 - Precipitation Reagent
45006 - Derivatisation Reagent 1
45007 - Derivatisation Reagent 2
45088 - Reduction Reagent
45099 - Internal Standard
39100 - 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

EC declaration valid until May 26th, 2027

Vers. 5.0

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Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

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