

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 I

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

CHROMSYSTEMS

DIAGNOSTICS BY HPLC & LC-MS/MS

Notified body: -

Gräfelfing, May 02nd, 2022



Michael Meier, Managing Director



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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

Vers. 5.0