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 64375, term "Glutathione IVD, kit, liquid chromatography"

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

Reagent Kit: **66000 - Glutathione in Whole Blood**

Calibrator: **66003 - Whole Blood Calibration Standard**

Controls:
0077 – Whole Blood Control Bi-Level (I+II)
0078 – Whole Blood Control Level I
0079 – Whole Blood Control -Level II

Products:
66001 - Mobile Phase
66002 - Mobile Phase (10x)
66004 - Internal Standard
66005 - Precipitation Reagent
66006 - Derivatisation Reagent 1
66007 - Derivatisation Reagent 2
66008 - Reduction Reagent
66100 - HPLC column
18066 - Precolumn cartridge

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 02nd, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 4.0

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