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: 54459, term "Vitamin C (ascorbic acid) IVD, kit, liquid chromatography"

EDMA-Nomenclature term: Other Vitamin Tests
EDMA-Nomenclature code: 12-07-02-90-00
IVDD Classification: *other product*

Reagent Kit: **65065 Vitamin C in Plasma/Serum**
65765/F – Vitamin C in Plasma/Serum - Automated HPLC

Calibrator: **65003 - Plasma Calibration Standard**

Controls: **0074 – Plasma Control Bi-Level (I+II)**
0075 – Plasma Control Level I
0076 – Plasma Control Level II

Products:

65001 - Mobile Phase
65002 - Mobile Phase
65044 - Internal Standard
65100 - HPLC Column
65757 - 96 well filter plates
65758 - Collection plates
65759 - Pierceable adhesive seals, for 96 well plates
18065 - 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

Vers. 2.0

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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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