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**

Calibrator: **65003 Plasma Calibration Standard**
Controls: **0074 Plasma Control Bi-Level (I+II)**
0075 Plasma Control Level I
0076 Plasma Control Level II

Components / Accessories

65001	Mobile Phase
65002	Mobile Phase
65044	Internal Standard
65100	HPLC Column
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

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, March 07th, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

SFDA Vers. 5.0