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 54436, term" Vitamin A (carotene) IVD, kit, spectrophotometry"

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

Reagent Kit:	**32000 - β-Carotene in Serum/Plasma**
Calibrator:	**32003 - Serum Calibration Standard**
Controls:	**0025 - ß-Carotene Serum Control, Bi-Level (I + II)** **0026 - ß-Carotene Serum Control, Level I** **0027 - ß-Carotene Serum Control, Level II**

Products:

32001 - Mobile Phase
32002 - Mobile Phase
32004 - Internal Standard
32005 - Precipitation Reagent
32006 - Extraction Buffer
32100 – HPLC column
18032 – 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, May 02nd, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 4.0

Chromsystems Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com