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 LC-MS/MS determination of:

GMDN code: 64766, term "Multiple vitamin IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

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

Reagent Kit: **87000 - *MassChrom*® Vitamins B1 and B6 in whole blood**
87000/DWP - *MassChrom*® Vitamins B1 and B6 in whole blood

Calibrator: **87039 - 6PLUS1® Multilevel Whole Blood Calibrator Set**

Controls: **0273 - *MassCheck*® Vitamins B1 and B6 Whole Blood Control Level I**
0274 - *MassCheck*® Vitamins B1 and B6 Whole Blood Control Level II
0275 - *MassCheck*® Vitamins B1 and B6 Whole Blood Control Level III

Products:

87001 - Mobile Phase A
87002 - Mobile Phase B
87046 - Internal Standard Set
87005 - Precipitation Reagent
87009 - Rinsing Solution
87057 - 96 Deep Well Plates
87058 - Collection Plates
87059 - Pierceable Adhesive Seals for 96 well plates
87100 - Analytical Column
87015 - Tuning Mix
87018 - Dilution Buffer
87019 - Adjustment Reagent

meet all applicable requirements of the directive 98/79/EC.

EC declaration valid until May 26th, 2027

Vers. 3.0

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

CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

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. 3.0

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