

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

DIAGNOSTICS BY HPLC & LC-MS/MS

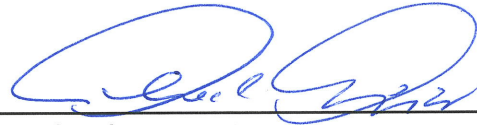
Conformity assessment procedure: Annex III of the directive 98/79/EC

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