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 61753, term "Methylmalonic acid (MMA) IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

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

Reagent Kit: **64000 – *MassChrom*® Methylmalonic Acid in plasma/ serum/urine**

Calibrator: **64028 – 3PLUS1® Multilevel Plasma Calibrator Set**
64029 – 3PLUS1® Multilevel Urine Calibrator Set

Control: **0313 – *MassCheck*® Methylmalonic Acid Plasma Control Bi-Level (I+II)**
0314 – *MassCheck*® Methylmalonic Acid Plasma Control Level I
0315 – *MassCheck*® Methylmalonic Acid Plasma Control Level II
0316 – *MassCheck*® Methylmalonic Acid Urine Control Bi-Level (I+II)
0317 – *MassCheck*® Methylmalonic Acid Urine Control Level I
0318 – *MassCheck*® Methylmalonic Acid Urine Control Level II

Products:
64001 – Mobile Phase A
64002 – Mobile Phase B
64004/P – Internal Standard
64007 – Dilution Buffer
64008 – Clean-Up Tubes
64009 – Rinsing Solution
64015 – Tuning Mix
64044/U – Internals Standard
64100 – Analytical Column

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

EC declaration valid until May 26th, 2027

Vers. 5.0

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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

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