

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 und Name: 55772 "Organic solvent metabolite IVD, kit, liquid chromatography"

EDMA Nomenclature term: Other Other Clinical Chemistry Reagents

EDMA Nomenclature code: 11-90-01-90-00

IVDD Classification: other product

Product name: **47000 - trans,trans-Muconic Acid in Urine**
47000/A1 - trans,trans-Muconic Acid in Urine
47000/A5 - trans,trans-Muconic Acid in Urine
47000/A9 - trans,trans-Muconic Acid in Urine

Calibrator: **47003 – Urine Calibrator Standard, t,t-Muconic Acid in urine**

Controls: **0161 - Urine Control Bi-Level (I+II), t,t-Muconic Acid in urine**
0162 - Urine Control Level I, t,t-Muconic Acid in urine
0163 - Urine Control Level II, t,t-Muconic Acid in urine

Components / Accessories

47001	Mobile Phase
47002	Mobile Phase (10x)
47004	Internal Standard
47004/A1	Internal Standard
47004/A5	Internal Standard
47004/A9	Internal Standard
47005	Wash Buffer 1
47005/A1	Wash Buffer 1

EC declaration valid until May 26th, 2027

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47005/A5	Wash Buffer 1
47005/A9	Wash Buffer 1
47006	Wash Buffer 2
47006/A1	Wash Buffer 2
47006/A5	Wash Buffer 2
47006/A9	Wash Buffer 2
47007	Wash Buffer 3
47007/A1	Wash Buffer 3
47007/A5	Wash Buffer 3
47007/A9	Wash Buffer 3
47008	Sample Clean Up Tubes
47008/A	Sample Clean Up Tubes with DEC caps
47009	Elution Buffer
47009/A1	Elution Buffer
47009/A5	Elution Buffer
47009/A9	Elution Buffer
47100	HPLC Column
18047	Precolumn Cartridge 4/10

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

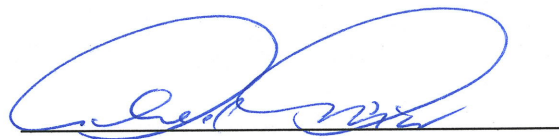
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 16th, 2022



Michael Meier, Managing Director