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 *55772*, term "Organic solvent metabolite IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Hippuric Acid
EDMA Nomenclature code:	12-09-02-08-00
IVDD Classification:	*other product*

Reagent Kit: 43000 - Hippuric Acid, Methylhippuric Acids, Mandelic Acid and Phenylglyoxylic Acid in Urine

Calibrator: 43003 - Urine Calibration Standard – Hippuric Acid, Methylhippuric Acids, Mandelic Acid, Phenylglyoxylic Acid in urine

Controls:
0141 - Urine Control Bi-Level (I+II) - Hippuric Acid, Methylhippuric Acids, Mandelic Acid, Phenylglyoxylic Acid in urine
0142 - Urine Control Level I - Hippuric Acid, Methylhippuric Acids, Mandelic Acid, Phenylglyoxylic Acid in urine
0143 - Urine Control Level II - Hippuric Acid, Methylhippuric Acids, Mandelic Acid, Phenylglyoxylic Acid in urine

Products:
43001 - Mobile Phase
43002 - Mobile Phase
43004 - Internal Standard
43100 - HPLC Column
18043 - 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

EC declaration valid until May 26th, 2027

Vers. 5.0

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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