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: 54342 "Pyridinoline (PYD) IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Pyridinoline
EDMA Nomenclature code:	12-06-03-16-00
IVDD Classification:	*other product*

Reagent Kits:
48000 – Crosslinks in Urine
48000/A1 - Crosslinks in Urine - automated HPLC
48000/A5 - Crosslinks in Urine - automated HPLC
48000/A9 - Crosslinks in Urine - automated HPLC

Calibrator:
48003 - Urine Calibration Standard

Controls:
0045 – Urine Control Bi-Level (I + II)
0046 – Urine Control Level I
0047 – Urine Control Level II

Products:
48001 - Mobile Phase
48002 - Mobile Phase (10x)
48004 - Internal Standard
48005 - Extraction Buffer
48006 - Wash Buffer
48007 - Elution Buffer
48008 - Sample Clean Up Columns
48008/A - Sample Clean Up Columns for Gilson ASPEC
48009 – Test Mix
48010 - Glass Tubes for hydrolysis
48011 - Screw Caps
48100 - HPLC Column
48405 - Extraction Buffer
48406 - Wash Buffer
18048 - Precolumn cartridge 4/10

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

EC declaration valid until May 26th, 2027

Vers. 5.0

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

EC declaration valid until May 26th, 2027

Vers. 5.0

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