

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.

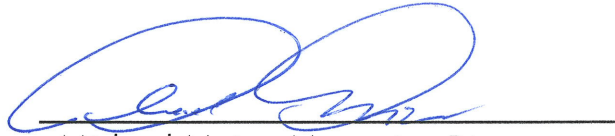
Conformity assessment procedure: Annex III of the directive 98/79/EC

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

