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"

Nomenclature term: Phenols
Nomenclature code: 12-09-02-11-00
Classification: *other product*

Product name: **41000 - o-Cresol, p-Cresol, Phenol in Urine**

Calibrator: **41003 - Urine Calibration Standard – o-Cresol, p-Cresol, Phenol in urine**

Controls: **0138 - Urine Control Bi-Level (I+II), o-Cresol, p-Cresol, Phenol in urine**
0139 - Urine Control Level I, o-Cresol, p-Cresol, Phenol in urine
0140 - Urine Control Level II, o-Cresol, p-Cresol, Phenol in urine

Components / Accessories

41001	Mobile Phase
41002	Mobile Phase
41004	Internal Standard
41055	Hydrolysis Reagent
41006	Stabilisation Buffer
41077	Hydrolysis vials, with crimp caps
41078	Hydrolysis vials, with snap ring caps
41100	HPLC Column
18041	Precolumn Cartridge 4/10

EC declaration valid until May 26th, 2027

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

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, July 20nd, 2023

Michael Meier, Managing Director

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Telefon: +49 89 18930-0
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