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 manual and automated sample preparation for the HPLC determination of:

GMDN Code und Name for reagent kit: 63881 "Polycyclic aromatic hydrocarbon (PAH) metabolite IVD, kit, liquid chromatography."

EDMA-Nomenclature term:	Other Other Clinical Chemistry Reagents
EDMA-Nomenclature code:	11-90-01-90-00
EDMA-Classification:	*other product*

Product name:	**53000 - 1-Hydroxypyrene in urine**
	53000/A1 - 1-Hydroxypyrene in urine
Calibrator:	**53003 - Urine Calibration Standard**
Controls:	**0177 - Urine Control Bi-Level (I+II), 1-Hydroxypyrene in urine**
	0178 - Urine Control Level I, 1-Hydroxypyrene in urine
	0179 - Urine Control Level II, 1-Hydroxypyrene in urine

Components / Accessories

53001	Mobile Phase
53004	Internal Standard
53005	Wash Buffer
53006	Hydrolysis Buffer
53007	Enzyme Solution
53009	Elution Buffer
53008	Sample Clean Up Columns
53008/A	Sample Clean Up Columns, with DEC-Caps
53100	HPLC Column
18053	Precolumn cartridge 4/10

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

EC declaration valid until May 26th, 2027

Vers. 3.0

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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

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