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 63823, term "Multiple biogenic amine neurotransmitter IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Other Toxicology
EDMA Nomenclature code:	12-09-02-90-00
IVDD Classification:	*other product*

Reagent Kit:
2020 – Metanephrines in Urine
2020/A1 - Metanephrines in Urine - automated HPLC
2020/A5 - Metanephrines in Urine - automated HPLC
2020/A9 - Metanephrines in Urine - automated HPLC

Calibrators:
2023 - Calibration Standard
2009 - Urine Calibration Standard

Controls:
0040 – Endocrine Urine Control, Normal Range
0050 – Endocrine Urine Control, Pathological Range

Products:
2010 - Tubes with screw caps for hydroylsis
2021 - Mobile Phase
2022 – Mobile Phase (10x)
2024 - Internal Standard
2024/A1 - Internal Standard for Gilson ASPEC
2025 - Neutralisation Buffer
2025/A1 - Neutralisation Buffer for Gilson ASPEC
2025/A5 - Neutralisation Buffer for Gilson ASPEC
2026 - Wash Buffer
2026/A1 - Wash Buffer for Gilson ASPEC
2026/A5 - Wash Buffer for Gilson ASPEC
2027 - Elution Buffer
2028 - Sample Clean Up Columns
2028/A - Sample Clean Up Columns for Gilson ASPEC
2044/HR - Internal Standard/High Resolution

EC declaration valid until May 26th, 2026

Vers. 4.0

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2099 - Interferences mix metanephrines
2120 - HPLC Column
18002 - 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

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