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/COMBI – Metanephrines in Urine, Combined Analysis**

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 hydrolysis**
**2024 - Internal Standard**
**2025 - Neutralisation Buffer**
**2026 - Wash Buffer**
**2027 - Elution Buffer**
**2028 - Sample Clean Up Columns**
**2029/COMBI - Stabilistation Reagent**
**2031/COMBI - Mobile Phase**
**2032/COMBI - Mobile Phase (10x)**
**2044/HR - Internal Standard/High Resolution**
**2099 - Interferences mix metanephrines**
**2130/COMBI - HPLC Column**

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*

EC declaration valid until May 26th, 2026

Vers. 3.0

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Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

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