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: Catecholamines
EDMA Nomenclature code: 12-09-02-04-00
IVDD Classification: *Other product*

Reagent Kit:
6000 – Catecholamines in Urine
6000/A1 - Catecholamines in Urine - automated HPLC
6000/A5 - Catecholamines in Urine - automated HPLC
6000/A9 - Catecholamines in Urine - automated HPLC

Calibrators:
6003 - Catecholamines Calibration Standard
6009 - Urine Calibration Standard

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

Products:
5001 - Mobile Phase
5002 – Mobile Phase (10x)
6004 - Internal Standard
6004/A1 - Internal Standard for Gilson ASPEC
6004/A5 - Internal Standard for Gilson ASPEC
6006 - Elution Buffer
6006/A9 - Elution Buffer for Gilson ASPEC
6007 - Sample Clean Up Columns
6007/A - Sample Clean Up Columns with DEC caps
6008/A1 - Neutralisation Buffer for Gilson ASPEC
6008/A9 - Neutralisation Buffer for Gilson ASPEC
6055 - Neutralisation Buffer
6100 - HPLC Column

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

EC declaration valid until May 26th, 2026

Vers. 5.0

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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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