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 60606, term "HVA/VMA/5HIAA IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Vanillylmandelic acid
EDMA Nomenclature code:	12-09-02-17-00
IVDD Classification:	*other product*

Reagent Kit:
1000/B – VMA, HVA und 5-HIAA in Urine
1000/B/A1 - VMA, HVA, 5-HIAA in Urine - automated HPLC
1000/B/A5 - VMA, HVA, 5-HIAA in Urine - automated HPLC
1000/B/A9 - VMA, HVA, 5-HIAA in Urine - automated HPLC

Calibrators:
1003/B - Calibration Standard
1009 - Urine Calibration Standard

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

Products:
1011 - Mobile Phase
1012 - Mobile Phase (10x)
1004/B - Internal Standard
1044/B/A1 - Internal Standard for Gilson ASPEC
1044/B/A5 - Internal Standard for Gilson ASPEC
1044/B/A9 - Internal Standard for Gilson ASPEC
1005 - Wash Buffer I
1005/A5 - Wash Buffer I for Gilson ASPEC
1006 - Wash Buffer II
1006/A - Wash Buffer II for Gilson ASPEC

EC declaration valid until May 26th, 2026

Vers. 4.1

Chromsystems
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1006/A5 - Wash Buffer II for Gilson ASPEC
1077 - Elution Buffer
1077/A5 - Elution Buffer for Gilson ASPEC
1013 – Finisher
1013/A5 - Finisher for Gilson ASPEC
1008 - Sample Clean Up Columns
1008/A - Sample Clean Up Columns for Gilson ASPEC
1100/B - HPLC Column
17002 - Precolumn cartridge 4/10
51303/B - Internal Standard (HICA)
1099 - Potential Optimisation Mix

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 16th, 2022

Michael Meier, Managing Director

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