

Addendum

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: 5-HIAA
EDMA Nomenclature code: 12-03-90-05-00
IVDD Classification: other product

Reagent Kit: 51000 - 5-HIAA in Urine
Calibrator: 1009 - Urine Calibration Standard
Controls: 0040 – Endocrine Urine Control, Normal Range
0050 – Endocrine Urine Control, Pathological Range

Products:
51001 - Mobile Phase
51002 - Mobile Phase (10x)
51003 - Internal Standard
51005 - Precipitation Reagent
51100 - HPLC Column

meet all applicable requirements of the directive 98/79/EC.
Conformity assessment procedure: Annex III of the directive 98/79/EC

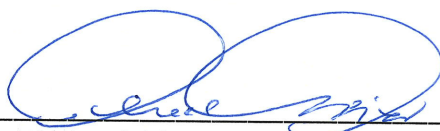
Applied harmonized standards:

EN ISO 13485, EN 13612, EN 13641, EN ISO 14971, EN 18113-1, EN 18113-2,
EN 15223-1, EN 17511, EN 23640

Notified body: -

Originally issued May 02nd, 2022 V3.0 is still valid until December 31st, 2028
according to regulation 2024/1860.

Gräfelfing, August 05th, 2026


Michael Meier, Managing Director

EC declaration valid until December 31th, 2028

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