

Addendum to

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

EDMA Nomenclature term: Serotonin
EDMA Nomenclature code: 12-03-90-17-00
IVDD Classification: *other product*

Reagent Kit: **4000 - Serotonin in Urine**

Calibrator: **3003 - Calibration Standard**
4009 - Urine Calibration Standard

Controls: **0040 - Endocrine Urine Control, Normal Range**
0050 - Endocrine Urine Control, Pathological Range

Products:
3031 - Mobile Phase
3032 - Mobile Phase (10x)
4004 - Internal Standard
4055 - Neutralisation Reagent
4006 - Wash Buffer
4007 - Elution Buffer
4008 - Sample Clean Up Columns
4100 - HPLC Column

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

EC declaration valid until December 31st, 2028

Addendum Vers. 1.0

The conformity was proved by the conformity assessment procedures referred to Annex III of the directive 98/79/EC.

This covers all calibrators, controls and components/accessories as listed on EC-Declaration of conformity V5.0 valid since May 2nd, 2022.

Originally issued May 2nd, 2022 V5.0 is still valid until December 31st, 2028 according to regulation 2024/1860.

Gräfelfing, August 8th, 2025



Michael Meier, Managing Director

EC declaration valid until December 31st, 2028

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