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/COMBI – Catecholamines in Urine, Combined Analysis

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

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

Products:
2031/COMBI - Mobile Phase
2032/COMBI - Mobile Phase (10x)
2130/COMBI - HPLC Column
6004 - Internal Standard
6006 - Elution Buffer
6007 - Sample Clean Up Columns
6010/COMBI - Stabilisation Reagent
6055 - Neutralisation Buffer

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 02nd, 2022

Michael Meier, Managing Director

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Vers. 2.0
Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)