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 54473, term "Multiple form 25-hydroxy Vitamin D IVD, kit, liquid chromatography"

EDMA Nomenclature term:	25-Hydroxyvitamin D
EDMA Nomenclature code:	12-06-03-10-00
IVDD Classification:	*other product*

Reagent Kit: **38038 - 25-OH-Vitamin D3/D2 in Serum/Plasma**

Calibrators:
62028 - Serum Calibrator Set
38033 - Serum Calibration Standard

Controls:
0028 - Serum Control Bi-Level (I + II)
0029 - Serum Control Level I
0030 - Serum Control Level II

Products:
38031 - Mobile Phase
38032 - Mobile Phase
38004 - Internal Standard
38005 - Precipitation Reagent
38006 - Wash Buffer 1
38007 - Wash Buffer 2
38009 - Elution Buffer
38008 - Sample Clean Up Columns
38130 - HPLC column
18038 – Precolumn cartridge

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

Conformity assessment procedure: Annex III of the directive 98/79/EC

EC declaration valid until May 26th, 2027

Vers. 4.0

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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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