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"

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

| | |
|---|---|
| Reagent Kit: | **38900/1000 - 25-OH-Vitamin D3/D2 in Serum/Plasma (Online Method)** |
| Calibrator: | **38033 - Serum Calibration Standard** |
| Controls: | **0028 – Serum Control Bi-Level (I + II)**<br>**0029- Serum Control Level I**<br>**0030 - Serum Control Level II** |

Products:

**38901 – Mobile Phase A**
**38902 – Mobile Phase B**
**38904 – Internal Standard**
**38910 – HPLC column**
**38920 – Trap 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: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 3.0

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