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 54444, term "Vitamin B2 (riboflavin) IVD, reagent"

EDMA Nomenclature term:	Vitamin B2
EDMA Nomenclature code:	12-07-02-02-00
IVDD Classification:	*other product*

Reagent Kit:	**37000 - Vitamin B_2 in Whole Blood**
Calibrator:	**37008 - Whole Blood Calibration Standard**
Controls:	**0033 - Whole Blood Control Level I + II** **0034 - Whole Blood Control Level I** **0035 - Whole Blood Control Level II**
Products:	**37011 - Mobile Phase** **37022 - Mobile Phase** **37005 - Extraction Buffer** **37007 - Precipitation Reagent** **37099 - Neutralisation Buffer** **37110 - HPLC column (equilibrated, with test chromatogram)** **17037 - Precolumn cartridge**

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. 4.0