

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 B₂ 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.

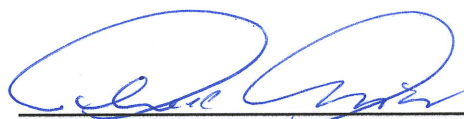
Conformity assessment procedure: Annex III of the directive 98/79/EC

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