EU-Declaration of Conformity

Manufacturer	Chromsystems Instruments & Chemicals GmbH
Address	Am Haag 12 82166 Gräfelfing, Germany
SRN (single registration number)	DE-MF-000010089

Order No.	Device Description	EMDN Code
Basic UDI-DI: 4250317350004Q		
35000	HPLC Reagent Kit Vitamin B1 in whole blood	W01010499
35000-BK	HPLC Basic Kit Vitamin B1 in whole blood	W01010499
35021	Mobile Phase	W01019099
35022	Mobile Phase	W01019099
37003	Extraction Buffer	W01019099
37004	Precipitation Reagent	W01019099
35005	Derivatisation Reagent 1	W01019099
35006	Derivatisation Reagent 2	W01019099
35009	Neutralisation Buffer	W01019099
35007	Stabilisation Buffer	W01019099
35110	HPLC column (equilibrated, with test chromatogram)	W01019099
37008	Whole Blood Calibration Standard	W0101050302
0033	Whole Blood Control Bi-Level (I+II)	W0101050299
0034	Whole Blood Control Level I	W0101050299
0035	Whole Blood Control Level II	W0101050299

Device Intended Purpose	The Chromsystems reagent kit 35000 "Vitamin B1 in whole blood" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of the physiologically active form of vitamin B1, thiamine pyrophosphate, in human whole blood samples. Sample preparation is carried out manually, and analytic separation is done via high performance liquid chromatography (HPLC). The test kit is intended to be used for screening and/or monitoring of vitamin B1 levels where indicated - in patients with suspected Vitamin B1 deficiency, - in patients with suspected Vitamin B1 excess, and/or - in patients under Vitamin B1 supplementation therapy.
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6
GMDN Code	54439: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of Vitamin B1 (thiamine) in a clinical specimen, using a liquid chromatography method.

Notified Body	TÜV Süd Product Service GmbH Ridlerstraße 65,	Identification No.	0123

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Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX	
Declarations		
This EU declaration of conformity is issued under the sole responsibility of the manufacturer. The devices that are covered by the present declaration are in conformity with the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).		
Following Common Specifications were considered as part of determining device conformity with the IVDR:		
Not applicable as no Common Specifications exist for the concerned device.		
Additional information	n/a	
This EU declaration of conformity is issued by		
Gräfelfing, October 31th, 2023 Michael Meier, Managing Director	Gräfelfing, October 31th, 2023 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	July 20th, 2027	Version: 1.0

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