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: 4250317520525C		
52052	**HPLC Reagent Kit Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma**	W01010499
52052/Premix	**HPLC Reagent Kit Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma with Pre-mixed Neutralisation Tubes**	W01010499
52752/F	**HPLC Reagent Kit Vitamins B1 and B6 in whole blood with 96 Well Filter Plates**	W01010499
52052-BK	**HPLC Basic Kit Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma**	W01010499
52052-PREMIX-BK	**(U)HPLC Basic Kit Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma**	W01010499
52052-F-BK	**(U)HPLC Basic Kit Vitamin B1 and Vitamin B6 in whole blood**	W01010499
52001	Mobile Phase A	W01019099
52022	Mobile Phase B	W01019099
36005	Plasma Calibration Standard	W0101050302
52003	Whole Blood Calibration Standard	W0101050302
52044	Internal Standard	W0101050399
52005	Precipitation Reagent	W01019099
52006	Neutralisation Reagent	W01019099
52906	Pre-mixed Neutralisation Tubes	W01019099
52007	Derivatisation Reagent 1	W01019099
52008	Derivatisation Reagent 2	W01019099
52744	Internal Standard Mix for 96 well filter plates	W0101050399
52705	Extraction Reagent for 96 well filter plates	W01019099
52706	Prep Solution for 96 well filter plates	W01019099
52707	Finisher 1 for 96 well filter plates	W01019099
52708	Finisher 2 for 96 well filter plates	W01019099
52709	Dilution Buffer for 96 well filter plates	W01019099

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52057	96 Well Filter Plates	W01019099
52058	Collection Plates	W01019099
52059	Pierceable Adhesive Seals, for 96 well plates	W01019099
52100	HPLC Column (equilibrated, with test chromatogram)	W01019099
0031	Plasma Control Bi-Level (I + II)	W0101050299
0038	Plasma Control Level I	W0101050299
0039	Plasma Control Level II	W0101050299
0164	Whole Blood Control Bi-Level (I + II)	W0101050299
0165	Whole Blood Control Level I	W0101050299
0167	Whole Blood Control Level II	W0101050299

Device Intended Purpose	The Chromsystems reagent kits 52052 and 52052/Premix "Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma" are in vitro diagnostic medical devices for professional use in clinical laboratories for the quantitative detection of the physiologically active forms of vitamin B1, thiamine pyrophosphate, in human whole blood samples and of vitamin B6, pyridoxal 5'-phosphate, in human whole blood or plasma 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 and/or B6 levels where indicated - in patients with suspected Vitamin B1 and/or B6 deficiency, - in patients with suspected Vitamin B1 and/or B6 excess, and/or - in patients under Vitamin B1 and/or B6 supplementation therapy. The Chromsystems reagent kit 52752/F "Vitamins B1 and B6 in whole blood" for sample preparation with 96 Well Filter Plates is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of the physiologically active forms of vitamin B1, thiamine pyrophosphate, and of vitamin B6, pyridoxal 5'-phosphate, 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 and/or B6 levels where indicated - in patients with suspected Vitamin B1 and/or B6 deficiency, - in patients with suspected Vitamin B1 and/or B6 excess, and/or - in patients under Vitamin B1 and/or B6 supplementation therapy. The test kit is further intended to be used as an aid to diagnosis of diseases for which determination of Vitamin B1 and/or B6 levels is indicated.		
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
GMDN Code	60484: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of multiple vitamins in a clinical specimen, using a liquid chromatography method.		
Notified Body	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany	Identification No.	0123
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX		

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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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