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: 4250317310003U		
31000/S	HPLC Reagent Kit Vitamin B6 in plasma/serum	W01010499
31000/WB	HPLC Reagent Kit Vitamin B6 in whole blood	W01010499
31000-BK	HPLC Basic Kit Vitamin B6 in plasma/serum/whole blood	W01010499
31001	Mobile Phase	W01019099
31002	Mobile Phase	W01019099
31003	Whole Blood Calibration Standard Vitamin B6 in whole blood	W0101050302
36005	Plasma Calibration Standard Vitamin B6 in plasma/serum	W0101050302
31004	Precipitation Reagent	W01019099
31005	Neutralisation Reagent	W01019099
31006	Derivatisation Reagent	W01019099
31100	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
0022	Whole Blood Control Bi-Level (I+II)	W0101050299
0023	Whole Blood Control Level I	W0101050299
0024	Whole Blood Control Level II	W0101050299

Device Intended Purpose	The Chromsystems reagent kit 31000/S "Vitamin B6 in serum/plasma – HPLC" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of the physiologically active form of vitamin B6, pyridoxal 5'-phosphate, in human serum 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 B6 levels where indicated - in patients with suspected Vitamin B6 deficiency, - in patients with suspected Vitamin B6 excess, and/or - in patients under Vitamin B6 supplementation therapy.

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)

	The Chromsystems reagent kit 31000/WB "Vitamin B6 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 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 B6 levels where indicated - in patients with suspected Vitamin B6 deficiency, - in patients with suspected Vitamin B6 excess, and/or - in patients under Vitamin B6 supplementation therapy.
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rule 6
GMDN Code	54450: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of vitamin B6 complex group, including pyridoxine, pyridoxal, pyridoxal phosphate, pyridoxamine and other B6-vitamers in a clinical specimen, using a liquid chromatography method.

Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	Identification No.	2797
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX Chapters I and III		
Certificates issued	EU Quality management System Certificate (IVDR) IVDR 838647		

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, March 23rd, 2026
Michael Meier, Managing Director

Gräfelfing, March 23rd, 2026
Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:	March 22nd, 2031	Version: 2.0

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