

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	<p>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).</p> <p>The test kit is intended to be used for screening and/or monitoring of vitamin B6 levels where indicated</p> <ul style="list-style-type: none"> - 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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	<p>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.</p> <p>Sample preparation is carried out manually, and analytic separation is done via high performance liquid chromatography (HPLC).</p> <p>The test kit is intended to be used for screening and/or monitoring of vitamin B6 levels where indicated</p> <ul style="list-style-type: none"> - 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-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 Chapters I and III	
Certificates issued	EU Quality management System Certificate (IVDR) No. V12 057136 0015 Rev01	
<p>Declarations</p> <p>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).</p> <p>Following Common Specifications were considered as part of determining device conformity with the IVDR:</p> <p>Not applicable as no Common Specifications exist for the concerned device.</p>		
Additional information	n/a	
<p>This EU declaration of conformity is issued by</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  Gräfelfing, March 01st, 2024 Michael Meier, Managing Director </div> <div style="text-align: center;">  Gräfelfing, March 01st, 2024 Dr. Ralf Fischer, PRRC </div> </div>		
EU declaration of conformity valid until:	July 20 th , 2027	Version: 1.1