



## 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		
52952/UHPLC	UHPLC Reagent Kit Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma	W01010499
52952/UHPLC/F	UHPLC Reagent Kit Vitamins B1 and B6 in whole blood with 96 Well Filter Plates	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
52911	Mobile Phase A	W01019099
52922	Mobile Phase B	W01019099
52044	Internal Standard	W0101050399
36005	Plasma Calibration Standard	W0101050302
52003	Whole Blood Calibration Standard	W0101050302
52005	Precipitation 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
52057	96 Well Filter Plates	W01019099
52058	Collection Plates	W01019099
52059	Pierceable Adhesive Seals for 96 well plates	W01019099
52210	UHPLC 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

<b>Device Intended Purpose</b>	<p>The Chromsystems reagent kits 52952/UHPLC "Vitamin B1 in whole blood, Vitamin B6 in whole blood/plasma" and 52952/UHPLC/F "Vitamins B1 and B6 in whole blood" 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 (52952/UHPLC and 52952/UHPLC/F) or plasma samples (52952/UHPLC). Sample preparation is carried out manually and analytic separation is done via ultra-high performance liquid chromatography (UHPLC). The test kit is intended to be used for screening and/or monitoring of vitamin B1 and/or B6 levels where indicated</p> <ul style="list-style-type: none"> <li>- in patients with suspected Vitamin B1 and/or B6 deficiency,</li> <li>- in patients with suspected Vitamin B1 and/or B6 excess, and/or</li> <li>- in patients under Vitamin B1 and/or B6 supplementation therapy.</li> </ul>		
<b>Risk Class</b>	B, as per EU Regulation 2017/746, Annex VIII, Rule 6		
<b>GMDN Code</b>	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.		
<b>Notified Body</b>	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany	<b>Identification No.</b>	0123
<b>Conformity Assessment</b>	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX		
<b>Declarations</b>			
<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>			
<b>Following Common Specifications were considered as part of determining device conformity with the IVDR:</b>			
Not applicable as no Common Specifications exist for the concerned device.			
<b>Additional information</b>	n/a		
<b>This EU declaration of conformity is issued by</b>			
 Gräfelfing, October 31 <sup>th</sup> , 2023 Michael Meier, Managing Director		 Gräfelfing, October 31 <sup>th</sup> , 2023 Dr. Ralf Fischer, PRRC	
<b>EU declaration of conformity valid until:</b>		July 20 <sup>th</sup> , 2027	<b>Version:</b> 1.0