# EU-Declaration of Conformity

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| Manufacturer | Chromsystems Instruments & Chemicals GmbH |
| Address | Am Haag 12<br>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**<br>**Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma** | W01010499 |
| 52952/UHPLC/F | **UHPLC Reagent Kit**<br>**Vitamins B1 and B6 in whole blood with 96 Well Filter Plates** | W01010499 |
| 52052-PREMIX-BK | **(U)HPLC Basic Kit**<br>**Vitamin B1 in whole blood and Vitamin B6 in whole blood/plasma** | W01010499 |
| 52052-F-BK | **(U)HPLC Basic Kit**<br>**Vitamin B1 and Vitamin B6 in whole blood** | W01010499 |
| 52911 | Mobile Phase A | W01019099 |
| 52922 | Mobile Phase B | W01019099 |
| 52044 | Internal Standard | W0101050399 |
| 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 |
| 0164 | Whole Blood Control Bi-Level (I + II) | W0101050299 |



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| 0165 | Whole Blood Control Level I | W0101050299 |
| 0167 | Whole Blood Control Level II | W0101050299 |
| Basic UDI-DI: 4250317310003U | | |
| 36005 | Plasma Calibration Standard | W0101050302 |
| 0031 | Plasma Control Bi-Level (I + II) | W0101050299 |
| 0038 | Plasma Control Level I | W0101050299 |
| 0039 | Plasma Control Level II | W0101050299 |

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| Device Intended Purpose | 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).<br>Sample preparation is carried out manually and analytic separation is done via ultra-high performance liquid chromatography (UHPLC).<br>The test kit is intended to be used for screening and/or monitoring of vitamin B1 and/or B6 levels where indicated<br>- in patients with suspected Vitamin B1 and/or B6 deficiency,<br>- in patients with suspected Vitamin B1 and/or B6 excess, and/or<br>- in patients under Vitamin B1 and/or B6 supplementation therapy. | | |
| 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. | | |
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| Notified Body | TÜV Süd Product Service GmbH<br>Ridlerstraße 65,<br>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)<br>No. V12 057136 0015 Rev01 | | |

**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.



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| Additional information | n/a |

This EU declaration of conformity is issued by

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| Gräfelfing, August 1st, 2024<br>Michael Meier, Managing Director | Gräfelfing, August 1st, 2024<br>Dr. Ralf Fischer, PRRC |

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| EU declaration of conformity valid until: | July 31th, 2029 | Version: 2.0 |



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