# 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: 42503176200054 | | |
| 62000 | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 in serum/plasma**<br>For 200 determinations | W01010499 |
| 62000/1000 | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 in serum/plasma**<br>For 1000 determinations | W01010499 |
| 62000/1000/F | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 in serum/plasma**<br>For sample preparation with 96 well filter plates<br>For 1000 determinations | W01010499 |
| 62062 | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 in serum/plasma**<br>For 200 determinations | W01010499 |
| 62062/1000 | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 in serum/plasma**<br>For 1000 determinations | W01010499 |
| 62062/1000/F | LC-MS/MS Reagent Kit<br>***MassChrom*® 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 in serum/plasma**<br>For sample preparation with 96 well filter plates<br>For 1000 determinations | W01010499 |
| Products individually available for reagent kit 62000 | | |
| 62001 | Mobile Phase A | W01019099 |
| 62002 | Mobile Phase B | W01019099 |
| 62003 | Precipitation Reagent | W01019099 |
| 62004 | Internal Standard | W0101050399 |
| 62009 | Rinsing Solution | W01019099 |
| 62015 | Tuning Mix, Analytes and Internal Standard | W0101050399 |
| 62057 | 96 Well filter plates | W01019099 |
| 62058 | Collection plates | W01019099 |
| 62059 | Pierceable adhesive seals | W01019099 |
| 62100 | Analytical column (equilibrated, with test chromatogram) | W01019099 |



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| 62110 | Trap column (equilibrated, with test chromatogram) | W01019099 |
| Products individually available for reagent kit 62062 | | |
| 62003 | Precipitation Reagent | W01019099 |
| 62009 | Rinsing Solution | W01019099 |
| 62011 | Mobile Phase A | W01019099 |
| 62017 | Tuning Mix, Analytes and Internal Standards | W0101050399 |
| 62022 | Mobile Phase B | W01019099 |
| 62045 | Internal Standard | W0101050399 |
| 62057 | 96 Well filter plates | W01019099 |
| 62058 | Collection plates | W01019099 |
| 62059 | Pierceable adhesive seals | W01019099 |
| 62110/Epi | Trap column (equilibrated with test chromatogram) | W01019099 |
| 62130 | Analytical column (equilibrated with test chromatogram) | W01019099 |
| Multilevel calibrators and MassCheck® controls | | |
| 62028 | 3PLUS1® Multilevel Serum Calibrator Set | W0101050301 |
| 62029 | 3PLUS1® Multilevel Serum Calibrator Set | W0101050301 |
| 62039 | 6PLUS1® Multilevel Serum Calibrator Set | W0101050301 |
| 0221 | ***MassCheck®*** 25-OH-Vitamin D3/D2 Serum Control Bi-Level (I + II) | W0101050299 |
| 0222 | ***MassCheck®*** 25-OH-Vitamin D3/D2 Serum Control Level I | W0101050299 |
| 0223 | ***MassCheck®*** 25-OH-Vitamin D3/D2 Serum Control Level II | W0101050299 |
| 0256 | ***MassCheck®*** 25-OH-Vitamin D3/D2 Serum Control Level III | W0101050299 |
| 0310 | ***MassCheck®*** 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 Serum Control Bi-Level (I + II) | W0101050299 |
| 0311 | ***MassCheck®*** 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 Serum Control Level I | W0101050299 |
| 0312 | ***MassCheck®*** 25-OH-Vitamin D3/D2 and 3-*epi*-25-OH-Vitamin D3 Serum Control Level II | W0101050299 |

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| Device Intended Purpose | 62000:<br>The "***MassChrom®*** reagent kit for the analysis of "25-OH-Vitamin D3/D2 in serum/plasma" reagent kit is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of 25-Hydroxycholecalciferol (25-OH-Vitamin D3) and 25-Hydroxyergocalciferol (25-OH-Vitamin D2) in human plasma or serum samples.<br>Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS).<br>The test kit is intended to be used for screening and/or monitoring of 25-OH-Vitamin D3/D2 levels where indicated<br>- in patients with suspected Vitamin D deficiency,<br>- in patients with suspected Vitamin D insufficiency,<br>- in patients with suspected Vitamin D excess, and/or<br>- in patients under Vitamin D supplementation therapy. |



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| | The test kit is further intended to be used as an aid to diagnosis of diseases for which determination of Vitamin D levels is indicated.<br><br>62062:<br>The "***MassChrom***® 25-OH-Vitamin D3/D2 and 3-epi-25-OH-Vitamin D3 in serum/plasma" reagent kit is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative detection of 25-Hydroxycholecalciferol (25-OH-Vitamin D3) and 25-Hydroxyergocalciferol (25-OH-Vitamin D2), as well as 3-epi-25-OH-Vitamin D3 in human plasma or serum samples.<br>Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS).<br>The test kit is intended to be used for screening and/or monitoring of 25-OH-Vitamin D3/D2 levels where indicated<br>- in patients with suspected Vitamin D deficiency,<br>- in patients with suspected Vitamin D insufficiency,<br>- in patients with suspected Vitamin D excess, and/or<br>- in patients under Vitamin D supplementation therapy.<br>The test kit is further intended to be used as an aid to diagnosis of diseases for which determination of Vitamin D levels is indicated.<br>This kit should be used, when the levels of 3-epi-25-OH-Vitamin D3 and 25-OH-Vitamin D3 are to be determined separately. |
| Risk Class | B, as per EU Regulation 2017/746, Annex VIII, Rule 6 |
| GMDN Code | 62018: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of multiple forms of 25-hydroxy vitamin D in a clinical specimen, using a liquid chromatography/mass spectrometry (LC/MS) method. It is used in the investigation of conditions associated with vitamin D deficiency and for the assessment of vitamin D status during supplementation therapy.<br>54473: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of multiple forms of 25-hydroxy vitamin D in a clinical specimen, using a liquid chromatography method.<br>54474: A material which is used to establish known points of reference for an assay intended to be used for the qualitative and/or quantitative detection of multiple forms of 25-hydroxy vitamin D in a clinical specimen.<br>54475: A material which is used to verify the performance of an assay intended to be used for the qualitative and/or quantitative detection of multiple forms of 25-hydroxy vitamin D in a clinical specimen.<br>54476: A substance or reactant intended to be used together with a parent IVD to perform a specific function in an assay that is used for the qualitative and/or quantitative detection of multiple forms of 25-hydroxy vitamin D in a clinical specimen. |
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| Notified Body | TÜV Süd Product Service GmbH<br>Ridlerstraße 65, |
| Identification No. | 0123 |



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| | 80339 Munich, Germany | |
| 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<br>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:<br>Not applicable as no Common Specifications exist for the concerned device. | | |
| Additional information | n/a | |
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| This EU declaration of conformity is issued by | | |
| Gräfelfing, March 01st, 2024<br>Michael Meier, Managing Director | Gräfelfing, March 01st, 2024<br>Dr. Ralf Fischer, PRRC | |
| EU declaration of conformity valid until: | July 20th, 2027 | Version: 1.1 |



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