



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: 42503176200054		
62000	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 in serum/plasma For 200 determinations	W01010499
62000/1000	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 in serum/plasma For 1000 determinations	W01010499
62000/1000/F	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 in serum/plasma For sample preparation with 96 well filter plates For 1000 determinations	W01010499
62062	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 and 3-epi-25-OH-Vitamin D3 in serum/plasma For 200 determinations	W01010499
62062/1000	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 and 3-epi-25-OH-Vitamin D3 in serum/plasma For 1000 determinations	W01010499
62062/1000/F	LC-MS/MS Reagent Kit MassChrom® 25-OH-Vitamin D3/D2 and 3-epi-25-OH-Vitamin D3 in serum/plasma For sample preparation with 96 well filter plates 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
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- <i>epi</i> -25-OH- Vitamin D3 Serum Control Bi-Level (I + II)	W0101050299
0311	MassCheck ® 25-OH-Vitamin D3/D2 and 3- <i>epi</i> -25-OH- Vitamin D3 Serum Control Level I	W0101050299
0312	MassCheck ® 25-OH-Vitamin D3/D2 and 3- <i>epi</i> -25-OH- Vitamin D3 Serum Control Level II	W0101050299

<p>Device Intended Purpose</p>	<p>62000: 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. Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS). The test kit is intended to be used for screening and/or monitoring of 25-OH-Vitamin D3/D2 levels where indicated</p> <ul style="list-style-type: none"> - in patients with suspected Vitamin D deficiency, - in patients with suspected Vitamin D insufficiency, - in patients with suspected Vitamin D excess, and/or - in patients under Vitamin D supplementation therapy. <p>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.</p> <p>62062: 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. Sample preparation is carried out manually, and analytic separation is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS). The test kit is intended to be used for screening and/or monitoring of 25-OH-Vitamin D3/D2 levels where indicated</p> <ul style="list-style-type: none"> - in patients with suspected Vitamin D deficiency, - in patients with suspected Vitamin D insufficiency, - in patients with suspected Vitamin D excess, and/or - in patients under Vitamin D supplementation therapy. <p>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. 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.</p>
<p>Risk Class</p>	<p>B, as per EU Regulation 2017/746, Annex VIII, Rule 6</p>

GMDN Codes	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>		
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		
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, August 5 th , 2022 Michael Meier, Managing Director		 Gräfelfing, August 5 th , 2022 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	July 20 th , 2027		Version: 1.0