

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: 4250317752226Q		
75222	LC-MS/MS-Reagent Kit MassChrom® Amino Acid Analysis in urine For 3 x 96 analyses	W01010499
75222/DWP	LC-MS/MS-Reagent Kit MassChrom® Amino Acid Analysis in urine with 96 Deep Well Plates For 3 x 96 analyses	W01010499
75211	MassChrom® Amino Acid Analysis Urine Set For 3 x 96 analyses	W01010499
75211/DWP	MassChrom® Amino Acid Analysis Urine Set with 96 Deep Well Plates For 3 x 96 analyses	W01010499
75001	Mobile Phase A	W01019099
75002	Mobile Phase B	W01019099
75009	Rinsing Solution	W01019099
75246	Internal Standard Set, containing: Internal Standard Mix (75204) Reconstitution Buffer (75206)	W0101050399
75205	Dilution Buffer	W01019099
75100	Analytical Column	W01019099
75058	Collection Plates	W01019099
75060	Pierceable Heat Seals, for 96 well plates	W01019099
75156	96 Deep Well Plates	W01019099
75015	Tuning Mix 1, Analytes and Internal Standards	W0101050399
75016	Tuning Mix 2, Analytes and Internal Standards	W0101050399
75017	Tuning Mix 3, Analytes and Internal Standards	W0101050399
75018	Tuning Mix 4, Analytes and Internal Standards	W0101050399
75019	Tuning Mix 5, Analytes and Internal Standards	W0101050399
75220	Tuning Mix 6, Analytes and Internal Standards	W0101050399
75212	Adjustment Reagent, for high AA concentrations	W01019099
75228	3PLUS1® Multilevel Urine Calibrator Set	W0101050301
0474	MassCheck® Amino Acid Analysis Urine Control Level I	W0101050207
0475	MassCheck® Amino Acid Analysis Urine Control Level II	W0101050207

0476	MassCheck® Amino Acid Analysis Urine Control Level III	W0101050207
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Device Intended Purpose	<p>The Chromsystems reagent kit “MassChrom® Amino Acid Analysis in urine” is an in vitro diagnostic medical product designed for professional users in clinical laboratories for the quantitative determination of 53 amino acids and metabolic products in human urine samples.</p> <p>Creatinine can be used for the normalization of urinary amino acid concentrations.</p> <p>Sample preparation is carried out manually, and analytical separation and specific detection of analytes is done via liquid chromatography with tandem mass spectrometry (LC-MS/MS).</p> <p>The kit is intended for the investigation and monitoring of the amino acid metabolic status of patients by determination of 1-methylhistidine, α-aminobutyric acid, β-aminoisobutyric acid, 3-methylhistidine, 4-hydroxyproline, acetyltyrosine, adenosylhomocysteine, alanine, allo-isoleucine, α-aminoadipic acid, anserine, arginine, argininosuccinic acid, asparagine, aspartic acid, β-alanine, carnosine, citrulline, cystathionine, cysteine sulphate, cystine, ethanolamine, γ-aminobutyric acid, glutamine, glutamic acid, glycine, histidine, homocitrulline, homocystine, hydroxykynurenine, hydroxylysine, isoleucine, kynurenine, leucine, lysine, methionine, ornithine, oxoproline/pyroglutamic acid, phenylalanine, phenylacetylglutamine, phosphoethanolamine, phosphoserine, pipercolic acid, proline, saccharopine, sarcosine, serine, taurine, threonine, tryptophan, tyrosine, valine and creatinine.</p> <p>It is furthermore intended as</p> <ul style="list-style-type: none"> - an aid to diagnosis of cystinuria, by determination of arginine-, cystine-, lysine-, and ornithine-concentrations normalized to creatinine, - an aid to diagnosis of lysinuric protein intolerance, by determination of creatinine-normalized arginine-, lysine-, and ornithine-concentrations, - an aid to differential diagnosis of Hartnup disorder versus other aminoacidurias (cystinuria and generalized aminoaciduria), by determination of alanine-, glycine-, and histidine-concentrations normalized to creatinine, and <p>and for monitoring of treatment efficacy in previously diagnosed cystinuria patients, by determination of cystine level.</p>	
Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rules 3j	
GMDN Code	64602 “Multiple amino acid IVD, kit, liquid chromatography/mass spectrometry (LC/MS)”	
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		
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, March 01 st , 2024 Michael Meier, Managing Director	Gräfelfing, March 01 st , 2024 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	July 20 th , 2027	Version: 1.1