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: 4250317NBS9Z		
57075	MS/MS Reagent Kit ***MassScreen®*** Amino Acids, Acylcarnitines EXTENDED from dried blood (non-derivatised) with 96 Well Plates	W01010499
57075-F	MS/MS Reagent Kit ***MassScreen®*** Amino Acids, Acylcarnitines EXTENDED from dried blood (non-derivatised) with 96 Well Filter Plates	W01010499
57075-ADO	MS/MS Reagent Kit ***MassScreen®*** Amino Acids, Acylcarnitines EXTENDED from dried blood (non-derivatised) incl. Ado, dAdo with 96 Well Plates	W01010499
57075-F-ADO	MS/MS Reagent Kit ***MassScreen®*** Amino Acids, Acylcarnitines EXTENDED from dried blood (non-derivatised) incl. Ado, dAdo with 96 Well Filter Plates	W01010499
0195	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED Dried Blood Spot Control Level I	W0101050299
0196	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED Dried Blood Spot Control Level II	W0101050299
0197	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED Dried Blood Spot Control Level III	W0101050299
0295	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED incl. Ado, dAdo Dried Blood Spot Control Level I	W0101050299
0296	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED incl. Ado, dAdo Dried Blood Spot Control Level II	W0101050299
0297	***MassCheck®*** Amino Acids, Acylcarnitines EXTENDED incl. Ado, dAdo Dried Blood Spot Control Level III	W0101050299
55011	Protective Sheets for 96 well plates	W01019099
57016	PEEK Prefilter 2 µm	W01019099
57001	Mobile Phase	W01019099
57007	Rinsing Solution	W01019099
57010	96 Well Plates	W01019099
57013	Extraction Buffer Succinylacetone	W01019099

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57014	Pierceable Heat Seals for 96 well plates	W01019099
57044	Internal Standard Succinylacetone (non-derivatised)	W0101050399
57055	96 Well Filter Plates	W01019099
57059	Cross-slitted Adhesive Seals for 96 well plates	W01019099
57074	Internal Standard Mix	W0101050399
57078	Extraction Buffer	W01019099
57080	Multilevel Dried Blood Spot Linearity Set	W0101050299
57090	Multilevel Dried Blood Spot Linearity Set incl. Ado, dAdo	W0101050299
57097-1	Tuning Mix 1 Analytes and Internal Standards	W0101050399
57097-2	Tuning Mix 2 Analytes and Internal Standards	W0101050399
57098	Tuning Mix Succinylacetone (non-derivatised) Analytes and Internal Standards	W0101050399
57474	Internal Standard Mix Ado, dAdo	W0101050399

Device Intended Purpose

The Chromsystems assay "***MassScreen***® Amino Acids, Acylcarnitines" is an in vitro diagnostic medical device designed for professional users in clinical laboratories for the quantitative determination of the below listed analytes in newborn blood samples dried on filter paper.

Sample preparation is carried out manually, and samples are analysed via tandem mass spectrometry (MS/MS).

The kit is intended for screening of newborns for inherited metabolic disorders within the first few days of life. A list of the metabolic disorders associated with the determined analytes is provided below.

Analyte (Synonym)	Abbreviation	Associated inborn error of metabolism**
Amino acids		
Alanine Sarcosine*	Ala Sar*	**PDHXD**, **PC**, MSUD, OH-PRO, NKHG, ARG, CIT I, CIT II, ASA, CPS, OTC
Arginine	Arg	**ARG**, **CIT II**, ASA, CIT I, PC
Argininosuccinic acid	Asa	**ASA**
Citrulline	Cit	**ASA**, **CIT I**, **CIT II**, **OTC**, **CPS**, **NAGS**, **PC**, CUD, HHH, GACR, HCY, TYR I, MET/MAT, TYR II, TYR III, HYRPRO1/HP-I, HYRPRO2/HP-II, ARG, Cbl E, Cbl G, Cbl D v1, MTHFR, 3MCC (mat), GA 1 (mat)
Glutamine‡ Lysine#*	Gln‡ Lys#*	**OTC‡**, **CPS ‡**, **NAGS‡**, PC#, LYS#, DE RED#, CIT I‡
Glutamic acid	Glu	**OTC**, **CPS**, CIT I, CIT II, PC
Glycine	Gly	**NKHG**, PA/PROP, MUT, Cbl A, B
Leucine‡ Isoleucine# Allo-Isoleucine Hydroxyproline*	Leu‡ Ile# Allo-Ile Hyp*	**MSUD** (‡#), **OH-PRO**, **PDHXD**(#), HCY‡#, PKU, H-PHE, BIOPT (BS), BIOPT (REG), MET/MAT‡# , Cbl E‡#, Cbl G‡#, Cbl D v1‡#, MTHFR‡#, TYR I, TYR II, TYR III
Methionine	Met	**HCY**, **MET/MAT**, **CIT II**, **MTHFR**, **Cbl E**, **Cbl G**, **Cbl D v1**, **GNMT**, **SAHH**, CIT I, TYR I, TYR II, TYR III, CUD, PA/PROP, MUT, Cbl A,B, Cbl C,D, OTC, CPS, B12 def (mat), PC
Ornithine	Orn	**HHH**, **GACR**, ARG, CIT II, CPS, OTC

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Phenylalanine	Phe	**PKU, H-PHE, BIOPT (BS), BIOPT (REG)**, MET/MAT, HCY, MSUD, ASA, CIT I, CIT II, OH-PRO, TYR I, TYR II, TYR III, ARG, OTC, CPS, PC, MTHFR, Cbl C,D, Cbl E, Cbl G, Cbl D v1, VAL, PDHXD, HHH, GACR, HYRPRO1/HP-I, HYRPRO2/HP-II
Proline	Pro	**HYRPRO1/HP-I, HYRPRO2/HP-II, PDHXD, PC**
Serine	Ser	**SER**, HHH, GACR
Tyrosine	Tyr	**TYR I, TYR II, TYR III, Tyr (trans)**, PKU, H-PHE, BIOPT (BS), BIOPT (REG), HCY, MSUD, MET/MAT, Cbl E, Cbl G, Cbl D v1, MTHFR, PDHXD, ASA, CIT I, CIT II, PC, OTC, CPS
Valine	Val	**MSUD, VAL, PDHXD**, TYR I, TYR II, TYR III
3-O-Methyldopa (*3-O-methyl-DOPA, 3-methoxytyrosine*)	3-OMD	**AADCD**
Carnitines		
Free carnitine	C0	**CUD, CPT Ia, CPT II, 3MCC, GA 1, PA/PROP, VLCAD, SCD**, CACT, BKT, HMG, GA 2, IVA, 2M3HBA, 2MBG, MUT, MCD, Cbl A,B, Cbl C,D, MCAD, EE, 3MGA, SUCLA2
Acetylcarnitine	C2	**CUD, CPT II, CACT, M/SCHAD**, MCAD, VLCAD, CPT Ia, MCKAT, SCAD, IVA, PA/PROP, 2MBG, IBG/IBDD, MUT, Cbl A,B, Cbl C,D, SUCLA2, MCD, GA 2, LCHAD, TFP, B12 def (mat), EE, 3MCC (mat), GA 1 (mat), BIOT, Cbl F, ECHS1D, TCN2
Propionylcarnitine	C3	**PA/PROP, MCD, MUT, Cbl A,B, Cbl C,D, CUD, SUCLA2, BIOT, B12 def (mat), Cbl F, TCN2**, 2MBG, IBG/IBDD, SCAD, IVA, CPT Ia, CPT II, CACT, MET/MAT, HCY, MTHFR, Cbl E, Cbl G, EE, GA 2, MAL, 3MCC (mat), GA 1 (mat)
Malonylcarnitine	C3DC‡	**M/SCHAD#, MAL‡, BKT#, HIBCHD#, ECHS1D, HADH**, GA 1‡, ‡2M3HBA#, MCKAT‡
3-Hydroxybutyrylcarnitine / 3-Hydroxyisobutyrylcarnitine*	C4OH#*	
Butyrylcarnitine# / Isobutyrylcarnitine‡*	C4*	**SCAD#, IBG/IBDD‡, EE#, GA 2**, GA 1, M/SCHAD, MCD, B12 def (mat), Cbl C,D, MUT, Cbl A,B, PA/PROP, MCKAT, MAL, IVA, VLCAD
Methylmalonylcarnitine / Succinylcarnitine	C4DC‡	**3MCC#, HMG#, BKT#, 2M3HBA#, 3MGA#, MCD#, BIOT#, SUCLA2‡, Cbl C,D, MUT‡, Cbl A,B‡**, GA 1#, GA 2#, MCAD
3-Hydroxyisovalerylcarnitine / 2-Methyl-3-hydroxybutyrylcarnitine*	C5OH#*	
Isovalerylcarnitine# / 2-Methylbutyrylcarnitine‡*	C5*	**IVA#, 2MBG‡, EE#, GA 2**, MCD, B12 def (mat), MUT, Cbl A,B, PA/PROP, VLCAD
Tiglylcarnitine‡ / 3-Methylcrotonylcarnitine#*	C5:1*	**BKT‡, 2M3HBA‡, 3MCC#, ECHS1D‡**
Glutarylcarnitine	C5DC‡	**GA 1‡, GA 2‡, M/SCHAD#, MCKAT#**, MAL‡, MCAD‡, HMG#
3-Hydroxyhexanoylcarnitine*	C6OH#*	
Hexanoylcarnitine	C6	**MCAD, GA 2**
Adipylcarnitine / 3-Methylglutarylcarnitine*	C6DC*	**HMG**
Octanoylcarnitine	C8	**MCAD, MCKAT, GA 2**, SCAD, 3MCC, HMG, BKT, GA 1, 2M3HBA, 3MGA, IBG/IBDD, MCD, M/SCHAD, EE, IVA, 2MBG, VLCAD
Octenoylcarnitine	C8:1	**MCKAT, GA 2**, MCAD
Decanoylcarnitine	C10	**MCAD, MCKAT, GA2**, DE RED, MAL
Decenoylcarnitine	C10:1	**MCAD, GA 2, MCKAT**
Decadienoylcarnitine	C10:2	**DE RED**
Dodecanoylcarnitine *(lauroylcarnitine)*	C12	**VLCAD, GA 2, CPT II, CACT**, MCKAT, GA 1
Dodecenoylcarnitine	C12:1	**VLCAD, GA 2**, LCHAD
Tetradecanoylcarnitine *(myristoylcarnitine)*	C14	**VLCAD, LCHAD, TFP, CPT II, CACT, GA 2**
Tetradecenoylcarnitine	C14:1	**VLCAD, LCHAD, TFP, GA 2**
Tetradecadienoylcarnitine	C14:2	**VLCAD, GA 2, LCHAD, TFP**

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3-Hydroxytetradecanoylcarnitine	C14OH	**LCHAD, TFP**
Hexadecanoylcarnitine *(palmitoylcarnitine)*	C16	**CUD, LCHAD, TFP, VLCAD, CPT Ia, CPT II, CACT, GA 2**, GA 1, PA/PROP, MUT, Cbl A,B, Cbl C,D, B12 def (mat), MCD, M/SCHAD, 3MCC (mat), SUCLA2, Cbl F
Hexadecenoylcarnitine	C16:1	**CPT II, CACT, CPT Ia, VLCAD, GA 2, LCHAD, TFP**
3-Hydroxyhexadecanoylcarnitine *(3-hydroxypalmitoylcarnitine)*	C16OH	**LCHAD, TFP**
3-Hydroxyhexadecenoylcarnitine Heptadecanoylcarnitine*	C16:1OH# C17‡*	**LCHAD#, TFP#, PA/PROP‡/#, MUT‡/#, Cbl A,B‡/#, Cbl C,D‡, B12 def (mat), TCN2‡**
Octadecanoylcarnitine *(stearoylcarnitine)*	C18	**CUD, CPT Ia, CPT II, CACT, LCHAD, TFP, VLCAD, GA 2**, GA 1, 3MCC (mat)
Octadecenoylcarnitine *(oleoylcarnitine)*	C18:1	**CUD, CPT Ia, CPT II, CACT, LCHAD, TFP, VLCAD, GA 2**, GA 1, 3MCC (mat)
Octadecadienoylcarnitine *(linoleoylcarnitine)*	C18:2	**CPT Ia, CPT II, CACT, LCHAD, VLCAD, TFP, GA 2, CUD**
3-Hydroxyoctadecanoylcarnitine *(3-hydroxystearoylcarnitine)*	C18OH	**LCHAD, TFP, CACT**
3-Hydroxyoctadecenoylcarnitine *(3-hydroxyoleoylcarnitine)*	C18:1OH	**LCHAD, TFP**
3-Hydroxyoctadecadienoylcarnitine *(3-hydroxylinoleoylcarnitine)*	C18:2OH	**LCHAD, TFP**
Eicosanoylcarnitine *(arachidoylcarnitine)*	C20	VLCAD
Docosanoylcarnitine *(behenoylcarnitine)*	C22	ALD, - AGS1 - AGS 8
Tetracosanoylcarnitine *(lignoceroylcarnitine)*	C24	ALD
Hexacosanoylcarnitine *(cerotoylcarnitine)*	C26	ZS/PBD-ZSS, ALD, AGS1 - AGS 8
Ketones		
Succinylacetone	SUAC	**TYR I**
Nucleosides		
Adenosine ***	Ado	**ADA-SCID**
2'-Deoxyadenosine ***	dAdo	**ADA-SCID**
Lysophospholipids		
1-Arachidoyl-2-hydroxy-sn-glycero-3-phosphocholine *(C20:0 lysophosphatidylcholine)*	C20:0 LPC	**ZS/PBD-ZSS**, Single PED, DDCH/CADDS, RDLKD, EMPF 1/EMPF 2, AGS1 - AGS 8, ALD
1-Behenoyl-2-hydroxy-sn-glycero-3-phosphocholine *(C22:0 lysophosphatidylcholine)*	C22:0 LPC	**ZS/PBD-ZSS**, Single PED, DDCH/CADDS, RDLKD, EMPF 1/EMPF 2, AGS1 - AGS 8, ALD
1-Lignoceroyl-2-hydroxy-sn-glycero-3-phosphocholine *(C24:0 lysophosphatidylcholine)*	C24:0 LPC	**ZS/PBD-ZSS**, Single PED, DDCH/CADDS, RDLKD, EMPF 1/EMPF 2, AGS1 - AGS 8, ALD
1-Hexacosanoyl-2-hydroxy-sn-glycero-3-phosphocholine *(C26:0 lysophosphatidylcholine)*	C26:0 LPC	**ALD, ZS/PBD-ZSS, Single PED, DDCH/CADDS, RDLKD, AGS1 - AGS 8**, EMPF 1/EMPF 2
Creatine and related metabolites		
Creatine	CRE	GAMT, GSD II
Creatinine	CRN	GSD II
Guanidinoacetic acid	GAA	**GAMT**

*: Isomers or isobars; using this method, they cannot be distinguished in the tandem mass spectrometry experiment; therefore, a summation estimate is provided in these cases; abbreviations correspond to the isobar/isomer in the same line, while associated diseases correspond to all isomers/isobars in the table row, unless stated otherwise (see ‡ and # below).

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**: Inborn errors of metabolism (IEMs) in bold are described to be screened for by using the indicated analyte as a primary marker, while others are described as secondary markers or part of informative ratios. Transient tyrosinemia and secondary carnitine deficiencies can be associated with IEMs, but are, themselves, not targets of the screening.

***: Ado and dAdo can only be determined when using the "Internal Standard Mix Ado, dAdo" and corresponding dried blood spot quality controls

‡ or #: Only the correspondingly labelled isomer/isobar is relevant for the indicated disease; in cases where only some, but not all publications specifically associate one of the isomers/isobars with the IEM, the corresponding label is in brackets.

Abbreviations of inborn errors of metabolism (OMIM codes in brackets: detailed information on the inborn errors of metabolism can be found via searching for the OMIM-codes on OMIM.org (Online Mendelian Inheritance in Man)):

2M3HBA (300438): 2-Methyl-3-hydroxybutyric aciduria/acidemia; **2MBG** (610006): 2-Methylbutyrylglycinuria; **3MCC** (210200; 210210): 3-Methylcrotonyl-CoA carboxylase deficiency (may include maternal (mat) type); **3MCC (mat)**: maternal 3-Methylcrotonyl-CoA carboxylase deficiency; **3MGA** (250950): 3-Methylglutaconic aciduria/acidemia type I; **AADCD** (608643): Aromatic L-amino acid decarboxylase deficiency; **ADA-SCID** (102700): Severe combined immunodeficiency due to adenosine deaminase deficiency; **AGS1 - AGS 8** (225750; 610181; 610329; 610333; 612952; 615010, 615846, 619486, 619487): Aicardi-Goutières Syndrome; **ALD** (300100): X-linked Adrenoleukodystrophy; **ARG** (207800): Argininemia; **ASA** (207900): Argininosuccinic acidemia; **B12 def (mat)**: B12 deficiency (maternal); **BIOPT (BS)** (261640): Disorders of biopterin defect in cofactor biosynthesis; **BIOPT (REG)** (261630): Biopterin defect in cofactor regeneration; **BIOT** (253260): Biotinidase deficiency; **BKT** (203750): beta-Ketothiolase deficiency / 3-oxothiolase deficiency; **CACT** (212138): Carnitine-acylcarnitine translocase deficiency; **Cbl A,B** (251100; 251110): Methylmalonic acidemia (cbl A, B disorders); **Cbl C,D** (277400; 277410): Methylmalonic acidemia (Cbl C,D) / Methylmalonic acidemia with homocystinuria (methylmalonyl-CoA mutase and homocysteine: MTHF methyltransferase/ MMADHC protein); **Cbl D v1** (277410): Methylcobalamin deficiency type cblDv1; **Cbl E** (236270): Methylcobalamin deficiency type cblE; **Cbl F** (277380): Methylmalonic acidemia with homocystinuria, cblF type; **Cbl G** (250940): Methylcobalamin deficiency type cblG; **CIT I** (215700): Citrullinemia type I; **CIT II** (605814): Citrullinemia type II; **CPS** (608307; 237300): Carbamoyl phosphate synthetase deficiency; **CPT Ia** (255120): Carnitine palmitoyltransferase type Ia deficiency; **CPT II** (255110; 608836; 600649): Carnitine palmitoyltransferase type II deficiency; **CUD** (212140): Carnitine uptake/transport defect (may include maternal type); **DDCH/CADDS** (300475): Contiguous ABCD1 DXS1357E deletion syndrome; **DE RED** (616034): 2,4-dienoyl-CoA reductase deficiency / dienoyl-CoA reductase deficiency caused by mitochondrial NAD kinase 2 deficiency; **ECHS1D** (616277): Short-chain enoyl-CoA hydratase deficiency; **EE** (602473): Ethylmalonic encephalopathy; **EMPF 1/EMPF 2** (614388; 617086): Peroxisomal fission defects / encephalopathy due to defective mitochondrial and peroxisomal fission; **GA 1** (231670): Glutaric acidemia type I (may include maternal type); **GA 1 (mat)**: Maternal glutaric acidemia type I; **GA 2** (231680): Multiple acyl-CoA dehydrogenase (MAD) deficiency/ glutaric acidemia type II; **GACR** (258870): Gyrate atrophy of the choroids and retina/ ornithine aminotransferase deficiency; **GAMT** (612736): Guanidinoacetate methyltransferase deficiency/ cerebral creatine deficiency syndrome 2; **GNMT** (606664): Glycine N-methyltransferase deficiency; **GSD II** (232300): Glycogen storage disease II / Pompe disease; **HCY** (236200): Homocystinuria (CBS); **HADH** (231530): Short chain 3-hydroxylacyl-CoA dehydrogenase deficiency; **HHH** (238970): Hyperornithinemia-hyperammonemia-homocitrullinuria syndrome; **HIBCHD** (250620): 3-hydroxyisobutyryl-CoA hydrolase deficiency; **HMG** (246450): 3-Hydroxy-3-methylglutaric acaduria; **H-PHE** (261600): (Benign) hyperphenylalaninemia; **HYRPRO1/HP-I** (239500): Hyperprolinemia type I; **HYRPRO2/HP-II** (239510): Hyperprolinemia type II; **IBG/IBDD** (611283): Isobutyryl-CoA dehydrogenase deficiency / Isobutyrylglycinuria; **IVA** (243500): Isovaleric academia; **LCHAD** (609016): Long-chain L-3-hydroxy acyl-CoA dehydrogenase deficiency; **LYS** (238700): Hyperlysinemia; **M/SCHAD** (601609): Medium/Short-chain L-3-hydroxy acyl-Co dehydrogenase deficiency; **MAL** (248360): Malonic aciduria/acidemia; **MCAD** (201450): Medium-chain acyl-CoA dehydrogenase deficiency; **MCD** (253270): Holocarboxylase synthetase/multiple carboxylase deficiency; **MCKAT** (602199): Medium-chain ketoacyl-CoA dehydrogenase/thiolase deficiency; **MET/MAT** (250850; 613752; 606664): Hypermethioninemia incl. Methionine adenosyltransferase deficiency; **MSUD** (248600): Maple syrup urine disease; **MTHFR** (236250): Methylenetetrahydrofolate reductase deficiency; **MUT** (251000): Methylmalonic acidemia; **NAGS** (237310): N-Acetylglutamate synthase deficiency; **NKHG** (605899): Non ketotic hyperglycinemia (synonym: glycine encephalopathy, GCE); **OH-PRO** (237000): Hydroxyprolinemia / 4-hydroxy-L-proline oxidase deficiency; **OTC** (300461; 311250): Ornithine transcarbamylase deficiency; **PA/PROP** (606054): Propionic acidemia; **PC** (266150): Pyruvate carboxylase deficiency; **PDHXD** (245348, 245349, 246900, 312170, 608782, 614111): Pyruvate dehydrogenase complex deficiency, including pyruvate dehydrogenase E2 deficiency, pyruvate dehydrogenase E3 deficiency, dihydrolipoamide dehydrogenase deficiency, pyruvate dehydrogenase E1-alpha deficiency, pyruvate dehydrogenase phosphatase deficiency, pyruvate dehydrogenase E1-beta deficiency; **PKU** (261600): Classic phenylketonuria; **RDLKD** (618863): Acyl-CoA Binding Domain Containing Protein 5 Deficiency / retinal dystrophy with leukodystrophy; **SAHH** (613752): S-adenosylhomocysteine hydrolase defciency; **SCAD**

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(201470): Short-chain acyl-CoA dehydrogenase deficiency; **SCD**: Secondary carnitine deficiencies (e.g., in organic acidemias and fatty acid oxidation disorders); **SER** (614023, 610992, 601815, 256520, 616038): Serine deficiency syndrome (incl. Neu-Laxova syndrome) caused by 3-phosphoglycerate dehydrogenase deficiency, 3-phosphoserine phosphatase deficiency or phosphoserine aminotransferase deficiency; **Single PED**: Single Peroxisomal Enzyme Deficiencies, includes D-bifunctional protein (DBP) deficiency (261515) and peroxisomal acyl-CoA oxidase (ACOX1) deficiency (264470); **SUCLA2** (603921): Succinyl-CoA synthetase deficiency; **TCN2** (275350): Transcobalamin II deficiency; **TFP** (609015): Trifunctional protein deficiency; **Tyr (trans)** (ORPHA:3402): transient Tyrosinemia; **TYR I** (276700): Tyrosinemia type I; **TYR II** (276600): Tyrosinemia type II; **TYR III** (276710): Tyrosinemia type III; **VAL** (277100): Valinemia; **VLCAD** (201475): Very long-chain acyl-CoA dehydrogenase deficiency; **ZS/PBD-ZSS** (214100; 214110; 614859; 614862; 614866; 614870; 614872; 614876; 614882; 614883; 614886): Zellweger syndrome / Peroxisome biogenesis disorders

Risk Class	C, as per EU Regulation 2017/746, Annex VIII, Rule 3m		
GMDN Code	60444 "Newborn metabolic screen/congenital disorder IVD, kit, mass spectrophotometry"		
Notified Body	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	Identification No.	2797
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) IVDR 838647		

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 23rd, 2026 Michael Meier, Managing Director	Gräfelfing, March 23rd, 2026 Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:	March 22nd, 2031	Version: 3.0

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