

Conformity Declaration

DiaSys Diagnostic Systems GmbH

Alte Strasse 9 · 65558 Holzheim · Germany

declares in our own responsibility conformity of the products listed below according to the essential requirements Annex I of the Directive 98/79/EC on *in vitro* diagnostic medical devices (IVD Directive).

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (product grouping common/other IVD products) of the Directive 98/79/EC, except of Point 6.

DiaSys Diagnostic Systems GmbH
Holzheim, 2022-04-06



Dr. Jan Gorka
Managing Director + CEO



List of products

Clinical Chemistry			
Product Name	Product code	Product Name	Product code
ALAT (GPT) FS (IFCC mod.)	1 2701...	HDL-C direct FS	1 3561...
Albumin FS	1 0220...	HDL-C Immuno FS	1 3521...
Alkaline phosphatase FS DGKC	1 0401...	Homocysteine FS	1 3409...
Alkaline phosphatase FS IFCC 37°C	1 0441...	β-Hydroxybutyrate FS	1 3701...
α-Amylase CC FS	1 0501...	β-Hydroxybutyrate 21 FS	1 3711...
ASAT (GOT) FS (IFCC mod.)	1 2601...	Iron FS Ferene	1 1911...
ATP Hexokinase FS	1 6201...	Lactate FS	1 4001...
Bicarbonate FS	1 0950...	LDH 21 FS	1 4251...
Bilirubin Auto Direct FS	1 0821...	LDH FS DGKC	1 4201...
Bilirubin Auto Total FS	1 0811...	LDH FS IFCC	1 4211...
Bilirubin Jendrassik-Gróf FS	1 0849...	LDL-c direct FS	1 4131...
Calcium AS FS	1 1130...	LDL-C Select FS	1 4121...
Calcium P FS	1 1181...	Lipase DC FS	1 4321...
Chloride 21 FS	1 1221...	Lp PLA ₂ FS	1 7181...
Cholesterol FS	1 1350... (5')	Magnesium XL FS	1 4610...
Cholesterol FS	1 1300... (10')	NEFA FS	1 5781...
Cholinesterase FS	1 1401...	Pancreatic amylase CC FS	1 0551...
CK-MB FS	1 1641...	Phosphate FS	1 5211...
CK-NAC FS	1 1601...	Phospholipids FS	1 5741...
Creatinine FS	1 1711...	Potassium FS	1 5221...
Creatinine PAP FS	1 1759...	Sodium FS	1 4808...
Ethanol FS	1 0881...	Total bile acids 21 FS	1 2238...
G6PDH	1 7900...	Total protein FS	1 2311...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	Total protein UC FS	1 0210...
GLDH FS DGKC	1 2411...	Triglycerides FS	1 5760... (5')
Glucose Gluc-DH FS	1 2531...	Triglycerides FS	1 5710... (10')
Glucose GOD FS	1 2550... (5')	UIBC FS	1 1921...
Glucose GOD FS	1 2500... (10')	Urea FS	1 3101...
Glucose Hexokinase FS	1 2511...	Urea CT FS	1 3115...
Glucose / Hemoglobin IS	1 2491...	Uric acid FS TBHBA	1 3021...
α-HBDH FS	1 3201...	Uric acid FS TOOS	1 3001...
HbA1c net FS	1 3348...		

Immunoturbidimetric Tests			
Product name	Product code	Product name	Product code
Albumin in Urine/CSF FS (Microalbumin)	1 0242...	oneHbA1c IS	1 3329...
Antistreptolysin O FS	1 7012...	oneHbA1c FS	1 3329...
Apolipoprotein A1 FS	1 7102...	Immunoglobulin A FS	1 7202...
Apolipoprotein B FS	1 7112...	Immunoglobulin E FS	1 7239...
Complement C3c FS	1 1802...	Immunoglobulin G FS	1 7212...
Complement C4 FS	1 1812...	Immunoglobulin M FS	1 7222...
CRP FS	1 7002...	Lp(a) 21 FS	1 7139...
CRP IS	2 7069...	Myoglobin FS	1 7098...
CRP U-hs	1 7045...	Prealbumin FS	1 0292...
Cystatin C FS	1 7158...	Procalcitonin FS	1 7318...
D-Dimer FS	1 7268...	Rheumatoid factor FS	1 7022...
Ferritin FS	1 7059...	SARS-CoV-2 UTAB FS	1 7508...
Ferritin SR	1 7245...	Transferrin FS	1 7252...

Supplementary reagents			
Product name	Product code	Product name	Product code
CK-MB DS	1 1690...	oneHbA1c Hemolyzing Solution	1 4570...
Cleaner A	1 8610...	HbA1c net Hemolyzing Solution	1 4590...
Cleaner B	1 8650...	HDL Precipitant	1 3540...
Cleaner 14	1 8620...	LDL Precipitant	1 4330...
Cleaner respons 920 / 940	1 8830...	Pyridoxal-5-phosphate FS	2 5010...
Glucose Hemolyzing Solution	1 2580...	SARS-CoV-2 UTAB Sample Dilution Matrix	1 7501...
G6PDH Hemolyzing Solution	1 7900...		

Calibrators			
Product Name	Product code	Product Name	Product code
TruCal Albumin U/CSF	1 9300...	TruCal G6PDH	1 7900...
TruCal Albumin U/CSF high	1 9300...	TruCal HbA1c liquid	1 3320...
TruCal Apo A1/B	1 7170...	TruCal HbA1c net	1 3350...
TruCal ASO	1 7010...	TruCal Homocysteine	1 3400...
TruCal CK-MB	5 9450...	TruCal IgE	1 7230...
TruCal CRP	1 7000...	TruCal Lipid	1 3570...
TruCal CRP 150	1 7000...	TruCal Lp(a) 21	1 7140...
TruCal CRP high	1 7000...	TruCal Myoglobin	1 7030...
TruCal CRP hs	1 7080...	TruCal PCT	1 7310...
TruCal CRP U	1 7040...	TruCal Protein	5 9200...
TruCal Cystatin C	1 7150...	TruCal Protein high	5 9200...
TruCal D-Dimer	1 7260...	TruCal RF	1 7020...
TruCal E	1 9310...	TruCal SARS-CoV-2	1 7500...
TruCal Ferritin	1 7050...	TruCal TBA	1 2240...
TruCal Ferritin SR	1 7240...	TruCal U	5 9100...

Controls			
Product Name	Product code	Product Name	Product code
TruLab Albumin U/CSF Level 1	5 9710...	TruLab HbA1c net Level 2	5 9940...
TruLab Albumin U/CSF Level 2	5 9720...	TruLab Homocysteine Level 1	5 9770...
TruLab Bicarbonate	5 9700...	TruLab Homocysteine Level 2	5 9780...
TruLab CRP Level 1	5 9600...	TruLab L Level 1	5 9020...
TruLab CRP Level 2	5 9610...	TruLab L Level 2	5 9030...
TruLab CRP hs Level 1	5 9730...	TruLab Lp(a) Level 1	5 9830...
TruLab CRP hs Level 2	5 9740...	TruLab Lp(a) Level 2	5 9840...
TruLab Cystatin C Level 1	5 9870...	TruLab N	5 9000...
TruLab Cystatin C Level 2	5 9880...	TruLab P	5 9050...
TruLab D-Dimer Level 1	5 9810...	TruLab PCT Level 1	5 9970...
TruLab D-Dimer Level 2	5 9820...	TruLab PCT Level 2	5 9980...
TruLab Ethanol	5 0900...	TruLab Protein Level 1	5 9500...
	5 4020...	TruLab Protein Level 2	5 9510...
TruLab G6PDH	1 7900...	TruLab SARS-CoV-2 Level 1	5 1750...
TruLab HbA1c liquid Level 1	5 9790...	TruLab SARS-CoV-2 Level 2	5 1760...
TruLab HbA1c liquid Level 2	5 9800...	TruLab Urine Level 1	5 9170...
TruLab HbA1c net Level 1	5 9930...	TruLab Urine Level 2	5 9180...

Standards			
Product Name	Product code	Product Name	Product code
Albumin Standard FS	1 0200...	β-Hydroxybutyrate Standard FS	1 3700...
ATP Standard FS	1 6200...	Iron Standard FS	1 1900...
Bicarbonate Standard FS	1 0950...	Magnesium Standard FS	1 4600...
Calcium Standard FS	1 1100...	NEFA Standard FS	1 5780...
Cholesterol Standard FS	1 1300...	Phosphate Standard FS	1 5210...
Creatinine Standard FS	1 1700...	Phospholipids Standard FS	1 5740...
Ethanol Standard FS (0,5 mg/mL)*	1 0890...	Total protein Standard FS	1 2300...
	1 4010...		
Ethanol Standard FS (1 mg/mL)*	1 0910...	Total protein UC Standard FS	1 0260...
	1 4030...		
Ethanol Standard FS (2 mg/mL)*	1 0920...	Triglycerides Standard FS	1 5700...
	1 4040...		
Ethanol Standard FS (3 mg/mL)*	1 0930...	Urea Standard FS	1 3100...
	1 4050...		
Glucose Standard FS	1 2500...	Uric acid Standard FS	1 3000...

Special products			
Product name	Product code	Product name	Product code
Selectra vials 10 mL	1 8700...	Selectra vials 25 mL	1 8700...

*not part of product name

“List of Applied Standards” is available on www.diasys-diagnostics.com

Amendment 01 to Conformity Declaration

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 · 65558 Holzheim · Germany

DiaSys Diagnostic Systems GmbH
Holzheim, 2022-07-27



Dr. Jan Gorka
CEO & Managing Director

List of products that have been removed from CE declaration (issued 2022-04-06) due to discontinuation:

Clinical Chemistry	
Product Name	Product code
N/A	N/A

Immunoturbidimetric Tests	
Product Name	Product code
N/A	N/A

Supplementary reagents	
Product Name	Product code
Cleaner 14	1 8620...

Calibrators	
Product Name	Product code
N/A	N/A

Controls	
Product Name	Product code
N/A	N/A

Standards	
Product Name	Product code
N/A	N/A

Special products	
Product Name	Product code
N/A	N/A

**not part of product name*

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Amendment 02 to Conformity Declaration

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 · 65558 Holzheim · Germany

DiaSys Diagnostic Systems GmbH
Holzheim, 2023-01-11

A handwritten signature in blue ink, appearing to read 'Jan Gorka', written over the printed name and title.

Dr. Jan Gorka
CEO & Managing Director

List of products that have been removed from CE declaration (issued 2022-04-06) due to discontinuation:

Clinical Chemistry	
Product Name	Product code
N/A	N/A

Immunoturbidimetric Tests	
Product Name	Product code
SARS-CoV-2 UTAB FS	1 7508...

Supplementary reagents	
Product Name	Product code
SARS-CoV-2 UTAB Sample Dilution Matrix	1 7501...

Calibrators	
Product Name	Product code
TruCal SARS-CoV-2	1 7500...

Controls	
Product Name	Product code
N/A	N/A

Standards	
Product Name	Product code
N/A	N/A

Special products	
Product Name	Product code
N/A	N/A

**not part of product name*

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