

Conformity Declaration

DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the product

respons[®] 910

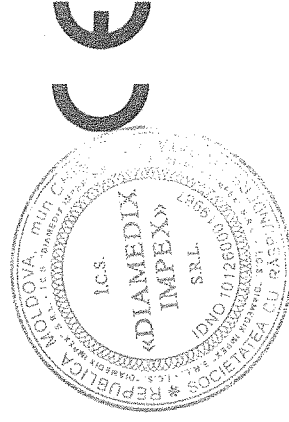
- Analyzer
- Accessories
- reagents as listed on page 2

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 of the Directive 98/79/EC (product grouping common/other IVD products), except of Point 6.

DiaSys Diagnostic Systems GmbH
Holzheim, 2020-08-12



Peter Zöllner
Managing Director & CEO

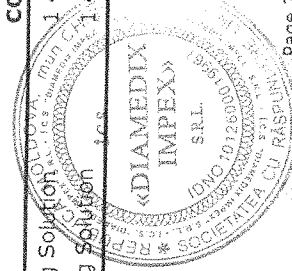


List of parameter

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...
Albumin in Urine/CSF FS (Microalbumin)	1 0242...	β-Hydroxybutyrate FS	1 3701...
Alkaline phosphatase FS IFCC 37°C	1 0441...	Immunoglobulin A FS	1 7202...
α-Amylase CC FS	1 0501...	Immunoglobulin E FS	1 7239...
Antistreptolysin O FS	1 7012...	Immunoglobulin G FS	1 7212...
Apolipoprotein A1 FS	1 7102...	Immunoglobulin M FS	1 7222...
Apolipoprotein B FS	1 7112...	Iron FS Ferene	1 1911...
ASAT (GOT) FS (IFCC mod.)	1 2601...	Lactate FS	1 4001...
Bicarbonate FS	1 0950...	LDH FS IFCC	1 4211...
Bilirubin Auto Direct FS	1 0821...	LDL-C Select FS	1 4121...
Bilirubin Auto Total FS	1 0811...	Lipase DC FS	1 4321...
Calcium P FS	1 1181...	Lp (a) FS	1 7139...
Chloride 21 FS	1 1221...	Lp-PLA ₂ FS	1 7181...
Cholesterol FS	1 1300...	Magnesium XL FS	1 4610...
Cholinesterase FS	1 1401...	Myoglobin FS	1 7098...
CK-MB FS	1 1641...	NEFA FS (Non-esterified fatty acids)	1 5781...
CK-NAC FS	1 1601...	Pancreatic amylase CC FS	1 0551...
Complement C3c FS	1 1802...	Phosphate FS	1 5211...
Complement C4 FS	1 1812...	Phospholipids FS	1 5741...
Creatinine FS (Jaffé)	1 1711...	Potassium FS	1 5221...
Creatinine PAP FS	1 1759...	Prealbumin FS	1 0292...
CRP FS	1 7002...	Rheumatoid factor FS	1 7022...
CRP U-hs	1 7045...	Sodium FS	1 4808...
Cystatin C FS	1 7158...	Total bile acids 21 FS	1 2238...
D-Dimer FS	1 7268...	Total protein FS	1 2311...
Ethanol FS	1 0881...	Total protein UC FS	1 0210...
Ferritin SR	1 7245...	Transferrin FS	1 7252...
Gamma-GT FS	1 2801...	Triglycerides FS	1 5710...
(Szasz mod./IFCC stand.)	1 2500...	UIBC FS	1 1921...
Glucose GOD FS	1 2511...	Urea FS	1 3101...
Glucose Hexokinase FS	1 3329...	Uric acid FS TOOS	1 3001...
one HbA1c FS	1 3348...		
HbA1c net FS			

Supplementary reagents

Product name	Product code	Product name	Product code
Cleaner A	1 8610...	oneHbA1c Hemolyzing Solution	1 4570...
Cleaner B	1 8650...	HbA1c net Hemolyzing Solution	1 4590...



Calibrators

Product name	Product code	Product name	Product code
TruCal Albumin U/CSF	1 9300...	TruCal Ferritin SR	1 7240...
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 IgE	1 7230...
TruCal CK-MB	5 9450...	TruCal Lipid	1 3570...
TruCal CRP	1 7000...	TruCal Lp(a) 21	1 7140...
TruCal CRP 150	1 7000...	TruCal Myoglobin	1 7030...
TruCal CRP high	1 7000...	TruCal Protein	5 9200...
TruCal CRP hs	1 7080...	TruCal Protein high	5 9200...
TruCal CRP U	1 7040...	TruCal RF	5 9200...
TruCal Cystatin C	1 7150...	TruCal TBA	1 7020...
TruCal D-Dimer	1 7260...	TruCal U	1 2240...
TruCal E	1 9310...		5 9100...

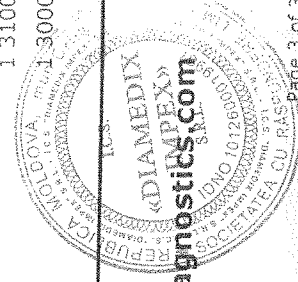
Controls

Product name	Product code	Product name	Product code
TruLab Albumin U/CSF Level 1	5 9710...	TruLab HbA1c liquid Level 2	5 9800...
TruLab Albumin U/CSF Level 2	5 9720...	TruLab HbA1c net Level 1	5 9930...
TruLab Bicarbonate	5 9700...	TruLab HbA1c net Level 2	5 9940...
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 Protein Level 1	5 9500...
TruLab D-Dimer Level 2	5 9820...	TruLab Protein Level 2	5 9510...
TruLab Ethanol	5 0900...	TruLab Urine Level 1	5 9170...
TruLab HbA1c liquid Level 1	5 9790...	TruLab Urine Level 2	5 9180...

Standards

Product name	Product code	Product name	Product code
Albumin Standard FS	1 0200...	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...
Ethanol Standard FS (1.0 mg/mL)*	1 0910...	Total protein UC Standard FS	1 0260...
Ethanol Standard FS (2.0 mg/mL)*	1 0920...	Triglycerides Standard FS	1 5700...
Ethanol Standard FS (3.0 mg/mL)*	1 0930...	Urea Standard FS	1 3100...
Glucose Standard FS	1 2500...	Uric acid Standard FS	1 3000...
β-Hydroxybutyrate Standard FS	1 3700...		

* not part of product name



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