

Conformity Declaration

DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the product

respons[®] 920

- Analyzer
- Accessories
- optional: ISE Unit
- reagents as 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 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 Zöller
Managing Director + CEO



List of parameters / reagents

Product Name	Product code	Product Name	Product code
ALAT (GPT) FS (IFCC mod.)	1 2701...	Glucose GOD FS	1 2550...
Albumin FS	1 0220...	Glucose Hexokinase FS	1 2511...
Albumin in Urine/CSF FS (Microalbumin)	1 0242...	HDL-C direct FS	1 3561...
Alkaline phosphatase FS IFCC 37°C	1 0441...	HDL-C Immuno FS	1 3521...
α -Amylase CC FS	1 0501...	oneHbA1c FS	1 3329...
Antistreptolysin O FS	1 7012...	Immunoglobulin A FS	17202...
Apolipoprotein A1 FS	1 7102...	Immunoglobulin E FS	1 7239...
Apolipoprotein B FS	1 7112...	Immunoglobulin G FS	1 7212...
ASAT (GOT) FS (IFCC mod.)	1 2601...	Immunoglobulin M FS	1 7222...
β -Hydroxybutyrate 21 FS	1 3711...	Iron FS Ferene	1 1911...
Bicarbonate FS	1 0950...	Lactate FS	1 4001...
Bilirubin Auto Direct FS	1 0821...	LDH FS IFCC	1 4211...
Bilirubin Auto Total FS	1 0811...	LDL-C Select FS	1 4121...
Complement C3c FS	1 1802...	Lipase DC FS	1 4321...
Complement C4 FS	1 1812...	Lp(a) 21 FS	1 7139...
Calcium P FS	1 1181...	Magnesium XL FS	1 4610...
Chloride 21 FS	1 1221...	Myoglobin FS	1 7098...
Cholesterol FS	1 1300...	Pancreatic amylase CC FS	1 0551...
Cholinesterase FS	1 1401...	Phosphate FS	1 5211...
CK-MB FS	1 1641...	Potassium FS	1 5221...
CK-NAC FS	1 1601...	Prealbumin FS	1 0292...
Creatinine FS (Jaffé)	1 1711...	Rheumatoid factor FS	1 7022...
Creatinine PAP FS	1 1759...	Sodium FS	1 4808...
CRP FS	1 7002...	Total protein FS	1 2311...
CRP U-hs	1 7045...	Transferrin FS	1 7252...
Cystatin C FS	1 7158...	Triglycerides FS	1 5710...
D-Dimer FS	1 7268...	Urea FS	1 3101...
Ferritin SR	1 7245...	Uric acid FS TOOS	1 3001...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	UIBC FS	1 1921...

Supplementary reagents			
Product name	Product code	Product name	Product code
Cleaner respons 920/940	1 8830...	ISE Urine diluent respons	1 3600...
oneHbA1c Hemolyzing Solution	1 4570...		

Calibrators			
Product Name	Product code	Product Name	Product code
TruCal Albumin U/CSF	1 9300...	TruCal E	1 9310...
TruCal Albumin U/CSF high	1 9300...	TruCal Ferritin SR	1 7240...
TruCal Apo A1/B	1 7170...	TruCal HbA1c liquid	1 3320...
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	1 7020...
TruCal Cystatin C	1 7150...	TruCal U	5 9100...
TruCal D-Dimer	1 7260...		

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 L Level 1	5 9020...
TruLab Bicarbonate	5 9700...	TruLab L Level 2	5 9030...
TruLab CRP Level 1	5 9600...	TruLab Lp(a) Level 1	5 9830...
TruLab CRP Level 2	5 9610...	TruLab Lp(a) Level 2	5 9840...
TruLab CRP hs Level 1	5 9730...	TruLab N	5 9000...
TruLab CRP hs Level 2	5 9740...	TruLab P	5 9050...
TruLab Cystatin C Level 1	5 9870...	TruLab Protein Level 1	5 9500...
TruLab Cystatin C Level 2	5 9880...	TruLab Protein Level 2	5 9510...
TruLab D-Dimer Level 1	5 9810...	TruLab Urine Level 1	5 9170...
TruLab D-Dimer Level 2	5 9820...	TruLab Urine Level 2	5 9180...
TruLab HbA1c liquid Level 1	5 9790...		

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...
β -Hydroxybutyrate Standard FS	1 3700...	Phosphate Standard FS	1 5210...
Calcium Standard FS	1 1100...	Total protein Standard FS	1 2300...
Cholesterol Standard FS	1 1300...	Triglycerides Standard FS	1 5700...
Creatinine Standard FS	1 1700...	Urea Standard FS	1 3100...
Glucose Standard FS	1 2500...	Uric acid Standard FS	1 3000...

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