

## Conformity Declaration

### DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the product

**respons<sup>®</sup>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, 2016-07-21



Peter Zöller  
Managing Director + CEO



## List of parameter

Product Name	Product code	Product Name	Product code
ALAT (GPT) FS (IFCC mod.)	1 2701...	HDL-C Immuno FS	1 3521...
Albumin FS	1 0220...	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...	Lipoprotein (a) FS	1 7139...
Chloride 21 FS	1 1221...	Magnesium XL FS	1 4610...
Cholesterol FS	1 1300...	Albumin in Urine/CSF FS (Microalbumin)	1 0242...
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 protein FS	1 2311...
D-Dimer FS	1 7268...	Total protein UC FS	1 0210...
Ethanol FS	1 0881...	Transferrin FS	1 7252...
Ferritin SR	1 7245...	Triglycerides FS	1 5710...
TruCal Ferritin SR	1 7240...	UIBC FS	1 1921...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	Urea FS	1 3101...
Glucose GOD FS	1 2500... (10')	Uric acid FS TOOS	1 3001...
Glucose Hexokinase FS	1 2511...	Cleaner A	1 8610...
HbA1c (one HbA1c) FS	1 3329...	Cleaner B	1 8650...

“List of Applied Standards” is available on [www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)