

# Conformity Declaration

## DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the product

**respons<sup>®</sup> 920**

- Analyzer
- Accessories
- optional: ISE Unit
- 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 parameters / reagents

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...	oneHbA1c FS	1 3329...
Alkaline phosphatase FS IFCC 37°C	1 0441...	Immunoglobulin A FS	17202...
$\alpha$ -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...
Complement C3c FS	1 1802...	Lp(a) 21 FS	1 7139...
Complement C4 FS	1 1812...	Albumin in Urine/CSF FS (Microalbumin)	1 0242...
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...
TruCal Ferritin SR	1 7240...	UIBC FS	1 1921...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	Cleaner A	1 8610...
Glucose GOD FS	1 2550...	Cleaner B	1 8650...
Glucose Hexokinase FS	1 2511...	Cleaner respons 920	1 8830...

## Additional for **respons<sup>®</sup>920** with ISE (Cat. no. 960 200)

Product Name	Product code	Product Name	Product code
Potassium electrode	960 403	Reference electrode	960 407
Sodium electrode	960 402	Reagent pack	960 430
Chloride electrode	960 405	ISE Urine diluent respons	1 3600...
Lithium electrode	960 406	ISE Cleaning solution respons	960 431

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