

Conformity Declaration

DiaSys Diagnostic Systems GmbH

Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the reagents listed on page 2

applicable on ***BioMajesty***[®] System

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, 2017-03-31

A handwritten signature in blue ink, appearing to read 'P. Zöller', is written over the name and title.

Peter Zöller
Managing Director + CEO



Product name	Product code	Product name	Product code
α -Amylase CC FS	1 0501...	HbA1c net	1 3348...
ALAT (GPT) FS (IFCC mod.)	1 2701...	HDL-C Immuno FS	1 3521...
Albumin FS	1 0220...	β -Hydroxybutyrate FS	1 3701...
Albumin in Urine/CSF FS (Microalbumin)	1 0242...	β -Hydroxybutyrate 21 FS	1 3711...
Alkaline phosphatase FS IFCC 37°C	1 0441...	Immunoglobulin A FS	1 7202...
Antistreptolysin O FS	1 7012...	Immunoglobulin E FS	1 7239...
Apolipoprotein A1 FS	1 7102...	Immunoglobulin M FS	1 7222...
Apolipoprotein B FS	1 7112...	Immunoglobulin G FS	1 7212...
ASAT (GOT) FS (IFCC mod.)	1 2601...	Iron FS Ferene	1 1911...
Bicarbonate FS	1 0950...	Lactate FS	1 4001...
Bilirubin Auto Direkt FS	1 0821...	LDH FS IFCC	1 4211...
Bilirubin Auto Total FS	1 0811...	LDL-C Select FS	1 4121...
Calcium P FS	1 1181...	Lipase DC FS	1 4321...
Cholesterol FS	1 1300...	Lp(a) 21 FS	1 7139...
Cholinesterase FS	1 1401...	Magnesium XL FS	1 4610...
CK-MB FS	1 1641...	Myoglobin FS	1 7098...
CK-NAC FS	1 1601...	NEFA FS	1 5781...
Complement C3c FS	1 1802...	Pancreatic amylase CC FS	1 0551...
Complement C4 FS	1 1812...	Phosphate FS	1 5211...
Creatinine FS	1 1711...	Phospholipids FS	1 5741...
Creatinine PAP FS	1 1759...	Prealbumin FS	1 0292...
CRP FS	1 7002...	Rheumatoid factor FS	1 7022...
Cystatin C FS	1 7158...	Total protein FS	1 2311...
D-Dimer	1 7268...	Transferrin FS	1 7252...
Ethanol FS	1 0881...	Triglycerides FS	1 5710...
Ferritin FS	1 7059...	UIBC FS	1 1921...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	Urea FS	1 3101...
Glucose Hexokinase FS	1 2511...	Uric acid FS TOOS	1 3001...

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