

Conformity Declaration

DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

declares conformity of the products 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, except of Point 6.

Clinical Chemistry

ALAT (GPT) FS (IFCC mod.)	CK-MB FS	LDH FS DGKC
Albumin FS	CK-NAC FS	LDH FS IFCC
Alkaline phosphatase FS DGKC	Creatinine FS	LDL-C Select FS
Alkaline phosphatase FS IFCC mod. 37 °C	Creatinine PAP FS	Lipase DC FS
α -Amylase FS CNP-G3	Ethanol FS	Magnesium XL FS
α -Amylase CC FS	Free cholesterol FS	NEFA FS
ASAT (GOT) FS (IFCC mod.)	Free glycerol FS	Pancreatic amylase CC FS
ATP Hexokinase FS	Gamma-GT FS (Szasz mod./IFCC stand.)	Phosphate FS
Bicarbonate FS	GLDH FS DGKC	Phospholipids FS
Bile acids	Glucose Gluc-DH FS	Total protein FS
Bilirubin Auto Direct FS	Glucose GOD FS	Total protein UC FS
Bilirubin Auto Total FS	Glucose Hexokinase FS	Triglycerides FS
Bilirubin Jendrassik Gróf FS	α -HBDH FS	UIBC FS
Calcium AS FS	HDL-C Immuno FS	Urea FS
Calcium CPC FS	Hemoglobin FS	Urea CT FS
Calcium P FS	Homocysteine FS	Uric acid FS TBHBA
Chloride FS	β -Hydroxybutyrate FS	Uric acid FS TOOS
Cholesterol FS	Iron FS Ferene	
Cholinesterase FS	Lactate FS	

Immunoturbidimetric Tests

Albumin in Urine/CSF FS	CRP U-hs	Lp(a) FS
Antistreptolysin O FS	Ferritin FS	Lp (a) 21 FS
Apolipoprotein A1 FS	oneHbA1c FS	Myoglobin FS
Apolipoprotein B FS	Immunoglobulin A FS	Prealbumin FS
Complement C3c FS	Immunoglobulin E FS	Rheumatoid factor FS
Complement C4 FS	Immunoglobulin G FS	Transferrin FS
CRP FS	Immunoglobulin M FS	

Special products

Urea test strips	Urinary calculi analysis
------------------	--------------------------

Calibrators

TruCal Albumin U/CSF	TruCal CRP U	TruCal Lp (a) 21
TruCal Apo A1/B	TruCal Ferritin	TruCal Myoglobin
TruCal ASO	TruCal HbA1c liquid	TruCal Phospholipids
TruCal CRP	TruCal HDL/LDL	TruCal Protein
TruCal CRP high	TruCal Homocysteine	TruCal Protein high
TruCal CRP 150	TruCal IgE	TruCal RF
TruCal CRP hs	TruCal Lp(a)	TruCal U

Controls

TruLab Albumin U/CSF	TruLab HbA1c liquid	TruLab P
TruLab Bicarbonate	TruLab Homocysteine	TruLab Protein
TruLab CRP	TruLab L	TruLab Urine
TruLab CRP hs	TruLab Lp(a)	
TruLab Ethanol	TruLab N	

Standards

Albumin Standard FS	Ethanol Standard FS	Phospholipids Standard FS
ATP Standard FS	Glucose Standard FS	Total protein Standard FS
Bicarbonate Standard FS	β -Hydroxybutyrate Standard FS	Total protein UC Standard FS
Calcium Standard FS	Iron Standard FS	Triglycerides Standard FS
Chloride Standard FS	Magnesium Standard FS	Urea Standard FS
Cholesterol Standard FS	NEFA Standard FS	Uric acid Standard FS
Creatinine Standard FS	Phosphate Standard FS	

Supplementary reagents

CK-MB DS	Glucose Hemolyzing Solution	LDL Precipitant
Creatinine FS Supplement	oneHbA1c Hemolyzing Solution	Pyridoxal-5-phosphate FS
Creatinine FS Urine Diluent	HDL Precipitant	Cleaner 14

DiaSys Diagnostic Systems GmbH
Holzheim, 2008-01-10


Dr. Günther Gorka
President



Reg. No. SY 60006714 0001
and SX 60010309 0001

Status 2008-01-10
replaces 2007-10-30

Appendix to

Conformity Declaration

DiaSys Diagnostic Systems

GmbH · Alte Strasse 9 · 65558 Holzheim · Germany

Applied harmonized standards within the European Community:

- DIN EN ISO 13485:** Medical devices - Quality management systems - Requirements for regulatory purposes
- DIN EN ISO 14971:** Medical devices – Application of risk management to medical devices
- DIN EN ISO 17511:** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- DIN EN 375:** Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- DIN EN 980:** Graphical symbols for use in the labelling of medical devices
- DIN EN 13640:** Stability testing of in vitro diagnostic reagent
- DIN EN 13641:** Elimination or reduction of risk of infection related to in vitro diagnostic reagents

Other standards applied:

- DIN EN ISO 9001:** Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration