

DECLARATION of CONFORMITY

Ref. No. CEDC-CA2009017A2-004

Date of Issue on: March 29, 2013

We,

JEOL Ltd., 1-2 Musashino 3-Chome, Akishima-City, Tokyo 196-8558, JAPAN declare under our sole responsibility that the product described below is in compliance with the following directives.

Product Name: Automatic Analyzer

Model Name: JCA-BM6010/C

Trade Mark: **JEOL**

Directive: In Vitro Diagnostic Medical Devices Directive (IVDD)
98/79/EC(Product grouping common/other IVD products)

Using the following standards

Quality Management System: EN ISO 13485: 2003

Risk Management System: EN ISO 14971: 2007

EMC Requirements: EN 61326-2-6: 2006 class A

EN 61000-4-2 Electrostatic discharge immunity

EN 61000-4-4 Electrical fast-transient/burst immunity

EN 61000-4-6 Immunity to conducted disturbances, induced by radio frequency field

EN 61000-4-3 Radiated, radio-frequency electromagnetic field immunity

EN 61000-4-11 Voltage dips, short interruptions immunity

EN 61000-4-5 Surge immunity

LVD Requirements: EN 61010-2-101: 2002

Directive: Low Voltage Directive (LVD)
2006/95/EC

Using the following standards

EN 61010-1: 2001

The company named above will keep on file for review the following technical documentation(s):

Amendment(A2) on February 24, 2011: Addition of three optional attachments.

Technical Documentations stored in :

Construction Data Form File No. CE-CA-017



Signature: Norio Watanabe

First Name: Norio

Last Name: Watanabe

Position/Title: General Manager,
Quality Assurance Office, JEOL Ltd.

Place: 1-2 Musashino 3-Chome, Akishima-City, Tokyo 196-8558 JAPAN



Composition of the equipment

System Unit **Model name :JCA-BM6010/C**

	No.	Model name	Product name	Console or Unit name	Note
Basic Instrument (BI)	1	CA-20151BM601C	BM Basic Unit	Consumable 1. Electrode Na 2. Electrode K 3. Electrode CL 4. Electrode Ref. 5.ISE standards 6.ISE buffers 7.ISE internal standards 8.Cleaning solutions	*1
	2	CA-27281SFT	08 System Software		
	3	CA-26211RTN12	Reagent table standard12		
	4	-	Operation Computer		Local Supply
	5	-	Charater Printer		Local Supply
	6	-	Operation Monitor		Local Supply
	7	-	Operation Console		Local Supply
Initial Option (IO)					
Optional at tachment (OA)		CE-ATT-ME-014-01		EMC/LVD Check list for Attchments	

*1.BM Basic Unit contains ELA09,A1C system,sleep interface,accessory,external connection.

CE DECLARATION of CONFORMITY

Ref. No. MEQ-DOC-160001-01

Date of Issue on: June 28, 2016

We,
JEOL Ltd., 3-1-2 Musashino, Akishima, Tokyo 196-8558, JAPAN declare under our sole responsibility that the product described below is in compliance with the following directives.

Product Name: Automatic Analyzer

Model Name: JCA-BM6010/C

Trade Mark: 

Directive : Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Using the following standards

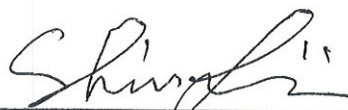
See Summary Technical Documentaion.

Directive : Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance

Using the following standards

EN 50581:2012

The company named above will keep on file for review the following technical documentation(s):
Technical Documentations stored in: MEQ-TDS-160001-02



Signature: Shin Saitoh

First Name : Shin

Last Name : Saitoh

Position/Title: Executive Officer,

Medical Equipment Business Operations, JEOL Ltd.

Place: 3-1-2 Musashino, Akishima, Tokyo, JAPAN

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


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

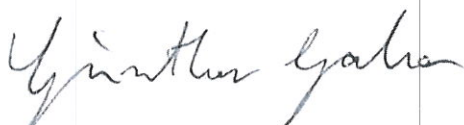
Conformity Declaration

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 · 65558 Holzheim · Germany

declares in our own responsibility 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 (product grouping common/other IVD products) of the Directive 98/79/EC, except of Point 6.

DiaSys Diagnostic Systems GmbH
Holzheim, 2018-06-25



Dr. Günther Gorka
CEO



List of products

Clinical Chemistry			
Product Name	Product code	Product Name	Product code
Acetaminophen FS	1 5819...	HbA1c net FS	1 3348...
ALAT (GPT) FS (IFCC mod.)	1 2701...	HDL-C Immuno FS	1 3521...
Albumin FS	1 0220...	HDL Precipitant	1 3540...
Alkaline phosphatase FS DGKC	1 0401...	Hemoglobin FS	2 2549...
Alkaline phosphatase FS IFCC 37°C	1 0441...	Homocysteine FS	1 3409...
α -Amylase CC FS	1 0501...	β -Hydroxybutyrate FS	1 3701...
ASAT (GOT) FS (IFCC mod.)	1 2601...	β -Hydroxybutyrate 21 FS	1 3711...
ATP Hexokinase FS	1 6201...	Iron FS Ferene	1 1911...
Bicarbonate FS	1 0950...	Lactate FS	1 4001...
Bile acids	1 2212...	LDH FS DGKC	1 4201...
Bilirubin Auto Direct FS	1 0821...	LDH FS IFCC	1 4211...
Bilirubin Auto Total FS	1 0811...	LDL-C Select FS	1 4121...
Bilirubin Jendrassik-Gróf FS	1 0849...	LDL Precipitant	1 4330...
Calcium AS FS	1 1130...	Lipase DC FS	1 4321...
Calcium P FS	1 1181...	Lp PLA ₂ FS	1 7181...
Chloride 21 FS	1 1221...	Magnesium XL FS	1 4610...
Cholesterol FS	1 1350... (5')	NEFA FS	1 5781...
Cholesterol FS	1 1300... (10')	Pancreatic amylase CC FS	1 0551...
Cholinesterase FS	1 1401...	Phosphate FS	1 5211...
CK-MB FS	1 1641...	Phospholipids FS	1 5741...
CK-NAC FS	1 1601...	Potassium FS	1 5221...
Creatinine FS	1 1711...	Sodium FS	1 4808...
Creatinine PAP FS	1 1759...	Total protein FS	1 2311...
Ethanol FS	1 0881...	Total protein UC FS	1 0210...
Gamma-GT FS (Szasz mod./IFCC stand.)	1 2801...	Triglycerides FS	1 5760... (5')
GLDH FS DGKC	1 2411...	Triglycerides FS	1 5710... (10')
Glucose Gluc-DH FS	1 2531...	UIBC FS	1 1921...
Glucose GOD FS	1 2550... (5')	Urea FS	1 3101...
Glucose GOD FS	1 2500... (10')	Urea CT FS	1 3115...
Glucose Hexokinase FS	1 2511...	Uric acid FS TBHBA	1 3021...
Glucose / Hemoglobin IS	1 2491...	Uric acid FS TOOS	1 3001...
α -HBDH FS	1 3201...		

Immunoturbidimetric Tests			
Product name	Product code	Product name	Product code
Albumin in Urine/CSF FS (Microalbumin)	1 0242...	Ferritin SR	1 7245...
Antistreptolysin O FS	1 7012...	oneHbA1c IS	1 3329...
Apolipoprotein A1 FS	1 7102...	oneHbA1c FS	1 3329...
Apolipoprotein B FS	1 7112...	Immunoglobulin A FS	1 7202...
Complement C3c FS	1 1802...	Immunoglobulin E FS	1 7239...
Complement C4 FS	1 1812...	Immunoglobulin G FS	1 7212...
CRP FS	1 7002...	Immunoglobulin M FS	1 7222...
CRP IS	2 7069	Lp(a) 21 FS	1 7139...
CRP U-hs	1 7045...	Myoglobin FS	1 7098...
Cystatin C FS	1 7158...	Prealbumin FS	1 0292...
D-Dimer FS	1 7268...	Rheumatoid factor FS	1 7022...
Ferritin FS	1 7059...	Transferrin FS	1 7252...

Supplementary reagents			
Product name	Product code	Product name	Product code
CK-MB DS	1 1690...	oneHbA1c Hemolyzing Solution	1 4570...
Cleaner A	1 8610...	HbA1c net Hemolyzing Solution	1 4590...
Cleaner B	1 8650...	HDL Precipitant	1 3540...
Cleaner 14	1 8620...	LDL Precipitant	1 4330...
Cleaner respons 920	1 8830...	Pyridoxal-5-phosphate FS	2 5010...
Glucose Hemolyzing Solution	1 2580...		

Calibrators			
Product Name	Product code	Product Name	Product code
TruCal Acetaminophen	1 5810...	TruCal Ferritin	1 7050...
TruCal Albumin U/CSF	1 9300...	TruCal Ferritin SR	1 7240...
TruCal Albumin U/CSF high	1 9300...	TruCal HbA1c liquid	1 3320...
TruCal Apo A1/B	1 7170...	TruCal HbA1c net	1 3350...
TruCal ASO	1 7010...	TruCal Homocysteine	1 3400...
TruCal CK-MB	5 9450...	TruCal IgE	1 7230...
TruCal CRP	1 7000...	TruCal Lipid	1 3570...
TruCal CRP 150	1 7000...	TruCal Lp(a) 21	1 7140...
TruCal CRP high	1 7000...	TruCal Myoglobin	1 7030...
TruCal CRP hs	1 7080...	TruCal Protein	5 9200...
TruCal CRP U	1 7040...	TruCal Protein high	5 9200...
TruCal Cystatin C	1 7150...	TruCal RF	1 7020...
TruCal D-Dimer	1 7260...	TruCal U	5 9100...
TruCal E	1 9310...	TruCal UIBC	1 1920...

<i>Controls</i>			
Product Name	Product code	Product Name	Product code
TruLab Acetaminophen Level 1	5 9370...	TruLab HbA1c net Level 1	5 9930...
TruLab Acetaminophen Level 2	5 9380...	TruLab HbA1c net Level 1	5 9940...
TruLab Albumin U/CSF Level 1	5 9710...	TruLab Homocysteine Level 1	5 9770...
TruLab Albumin U/CSF Level 2	5 9720...	TruLab Homocysteine Level 2	5 9780...
TruLab Bicarbonate	5 9700...	TruLab L Level 1	5 9020...
TruLab CRP Level 1	5 9600...	TruLab L Level 2	5 9030...
TruLab CRP Level 2	5 9610...	TruLab Lp(a) Level 1	5 9830...
TruLab CRP hs Level 1	5 9730...	TruLab Lp(a) Level 2	5 9840...
TruLab CRP hs Level 2	5 9740...	TruLab N	5 9000...
TruLab Cystatin C Level 1	5 9870...	TruLab P	5 9050...
TruLab Cystatin C Level 2	5 9880...	TruLab Protein Level 1	5 9500...
TruLab D-Dimer Level 1	5 9810...	TruLab Protein Level 2	5 9510...
TruLab D-Dimer Level 2	5 9820...	TruLab Urine Level 1	5 9170...
TruLab Ethanol	5 0900...	TruLab Urine Level 2	5 9180...
TruLab HbA1c liquid Level 1	5 9790...		
TruLab HbA1c liquid Level 2	5 9800...		

<i>Standards</i>			
Product Name	Product code	Product Name	Product code
Albumin Standard FS	1 0200...	β -Hydroxybutyrate Standard FS	1 3700...
ATP Standard FS	1 6200...	Iron Standard FS	1 1900...
Bicarbonate Standard FS	1 0950...	Magnesium Standard FS	1 4600...
Calcium Standard FS	1 1100...	NEFA Standard FS (Non-esterified fatty acids)	1 5780...
Cholesterol Standard FS	1 1300...	Phosphate Standard FS	1 5210...
Creatinine Standard FS	1 1700...	Phospholipids Standard FS	1 5740...
Ethanol Standard FS (0,5 mg/mL)*	1 0890...	Total protein Standard FS	1 2300...
Ethanol Standard FS (1 mg/mL)*	1 0910...	Total protein UC Standard FS	1 0260...
Ethanol Standard FS (2 mg/mL)*	1 0920...	Triglycerides Standard FS	1 5700...
Ethanol Standard FS (3 mg/mL)*	1 0930...	Urea Standard FS	1 3100...
Ethanol Standard FS (4 mg/mL)*	1 0940...	Uric acid Standard FS	1 3000...
Glucose Standard FS	1 2500...		

Special products			
Product name	Product code	Product name	Product code
Urea test strips	1 3129...	Selectra vials 10 mL	1 8700...
System solution Selectra	1 4560...	Selectra vials 25 mL	1 8700...

*not part of product name

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