

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: 

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