

EU Declaration of Conformity

Manufacturer's Name:	JEOL Ltd.
Address:	3-1-2 Musashino, Akishima, Tokyo 196-8558, JAPAN
SRN (Single Registration Number):	NL-AR-000023086
Authorised Representative's Name:	JEOL (EUROPE) B.V.
Address:	Lireweg 4, 2153 PH Nieuw-Vennep, The Netherlands
Basic UDI-DI:	4987762B04900KK
Name of the Device (s):	JCA-BM6010/C
Product Code:	CA-20151BM601C
Classification:	CLASS A
Notified Body Name:	N/A
Address:	N/A
Identification Number:	N/A
Conformity Assessment Procedure:	JEOL Ltd. applies the following procedure to demonstrate the compliance to the requirements in the Regulation (EU) 2017/746 and affixes the CE marking of conformity to its products. Class A: EU declaration of conformity in accordance with Annex II, III and IV
Intended purpose	The JCA-BM6010/C Clinical Chemistry Analyzer is an automatic chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. Applications include colorimetric, latex agglutination and ion selective electrode. This analyzer is intended for professional use in a laboratory environment only. Tests performed using this analyzer are intended for in vitro diagnostic use. As with all diagnostic tests, a definitive clinical diagnosis is not based on the results of a single test. Only a physician can make a diagnosis after evaluating all clinical and laboratory findings.

This declaration of conformity is issued under the sole responsibility of JEOL Ltd. We hereby declare that the medical device specified above meets the provisions of the following regulations and directives.

All supporting documentation is retained at the premises of the manufacturer.

Regulations/Directives:	Regulation (EU) 2017/746 Directive 2011/65/EU
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Signature:
FUJINO Kiyotaka



General Manager,
Medical Equipment Business Operations, JEOL Ltd.

Place of issue: 3-1-2 Musashino, Akishima,
Tokyo 196-8558, JAPAN

Date of issue: 2023/1/19

Supplied Accessories that are a part of this declaration of conformity:

Accessories

Reference number	Description
CA-20221JPNL	Front and side panels in EU member countries
CA-28031EU	(Power cable compliant to standards in EU member countries.
CA-27381SFTDS1	SOFTWARE DS1
CA-27781SFTLEN	STANDARD SOFTWARE
CA-26461RTND00	A type of the Reagent Tray Changeable from CA-26471RTND12 to this tray type.
CA-26471RTND12	A type of the Reagent Tray The standard tray type
CA-26481RTND24	A type of the Reagent Tray Changeable from CA-26471RTND12 to this tray type.
CA-26231RTND36	A type of the Reagent Tray Changeable from CA-26471RTND12 to this tray type.
CA-27611CPU	Windows7-compliant
CA-27731CPU	Windows10-compliant
CA-27691CPUACC	OPERATION COMPUTER
CA-27701TPLCD	TOUCH PANEL MONITOR
CA-21391RAMINI	RACK HANDLER RAMini basic unit
CA-21661MNJPNL	A component of RACK HANDLER RAMini basic unit
CA-21691MNEULB	A component of RACK HANDLER RAMini basic unit
CA-21411DPSTD	An optional part for RACK HANDLER RAMini
CA-21401TRY13	RACK TRAY13
CA-21171	CALIBRATION RACK
CA-21191	ADAPTABLE UNIT
CA-21221SRAC	SAMPLE RACK
CA-21291BUSH	BUSH ADAPTOR
780656644	Cuvette Wash Solution 7
781608074	Cuvette Wash Solution 3
780656652	Cuvette Conditioner EX
780654072	Reagent Probe Wash 1
780654081	Reagent Probe Wash 2
780654056	Reagent Probe Wash K
780654064	Reagent Probe Wash S
780656661	Lamp Coolant C
780609727	ISE Buffer (IS)
780609735	Internal Standard
780654099	ISE Detergent Solution
780654111	ISE Serum Standard Set (NA)
780654129	ISE Urine Standard Set
780654137	Sodium Electrode
780654145	Potassium Electrode
780654153	Chloride Electrode
780654161	Reference Electrode