



EU Declaration of Conformity

Manufacturer: **JVCKENWOOD Corporation** [SRN: -]
3-12, Moriya-cho, Kanagawa-ku, Yokohama-shi, Kanagawa,
221-0022, JAPAN

Authorised Representative: **JVCKENWOOD Deutschland GmbH** [SRN: -]
Konrad-Adenauer-Allee 1-11, 61118 Bad Vilbel, GERMANY

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Basic UDI-DI: CL-S1200xxxx: 4975769CL-S1200XA

Model name: **CL-S1200xxxx (CI-S1200)**

Trademark: **JVC**

Description: Medical Electrical Equipment:
78.4cm (30.9") Color LCD Monitor

Intended purpose: - displaying and viewing medical images for diagnosis
- digital mammography PACS, digital breast tomosynthesis
and modalities including FFDM

Accessory: power cord, DisplayPort cable x2, USB cable,
utility disk, installation manual, operation manual

Medical device risk class: **Class I**

The device that is covered by the present declaration is in conformity with the relevant Union legislation:

Regulation 2017/745 (medical devices)

harmonised standards and common specifications:	electromagnetic compatibility: EN 60601-1-2:2015 / Class B safety: EN 60601-1:2006 + A1:2013 + A12:2014 others: EN 62366:2008; EN 60601-1-6:2010 + A1:2015; EN 62304:2006
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Directive 2011/65/EU (restriction of the use of certain hazardous substances)

harmonised standards:	EN IEC 63000:2018
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Clinical study	N/A
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Notified body (where applicable):	N/A
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Notified body number:	N/A
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Conformity assessment procedure:	N/A
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Reference number of the certificate of notified body:	N/A
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Additional Information	The models "CL-S1200BGEA", "CL-S1200BGUA", and "CL-S1200BGJA" are identical to "CL-S1200xxxxx" in every aspect of attributes. The difference of the model suffix above means marketing area and surface treatment only.
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Signed for and on behalf of JVCKENWOOD Corporation:

Yokohama, December 23, 2020
Place, date of issue (MM/DD/YYYY)

Signature: 
Yorinobu Ueda
Manager
Quality Assurance Department
Healthcare Business Division
JVCKENWOOD Corporation