JVCKENWOOD

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-R190xxxxx: 4975769CL-R190W8

Model name:

CL-R190xxxxx (CL-R190)

Trademark:

JVC

Description:

Medical Electrical Equipment:

48cm (19") Color LCD Monitor

Intended purpose:

- displaying and viewing medical images for diagnosis

Accessory:

power cord, DVI cable, DisplayPort cable, USB cable,

AC adapter, Instruction 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

others:

EN 62366:2008; EN 60601-1-6:2010

Directive 2011/65/EU (restriction of the use of certain hazardous substances)

harmonised standards:

EN 50581:2012

Clinical study

N/A

Notified body (where applicable):

N/A

Notified body number:

N/A

Conformity assessment procedure:

N/A

Reference number of the certificate of notified body:

N/A

Additional Information

The models "CL-R190BN0EA" and "CL-R190BN0JA" are identical to

"CL-R190xxxxx" in every aspect of attributes.

The difference of the model suffix above means marketing area only.

Signed for and on behalf of JVCKENWOOD Corporation:

Yokohama,

2020/09/03

Place, date of issue (YYYY/MM/DD)

Signature:

Yorinobu Ueda Manager

Quality Assurance Department Healthcare Business Division

JVCKENWOOD Corporation