



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: DE-AR-000013568]
Konrad-Adenauer-Allee 1-11, 61118 Bad Vilbel, GERMANY

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

Series name & Basic UDI **CL-S500xxxxx (CL-S500): 4975769CL-S500W8**
Model name & UDI-DI **CL-S500BG0JA : 04975769460036 CL-S500BG2JA : 04975769462672**
CL-S500BG0UA : 00046838079962 CL-S500BG2UA : 00046838081026
CL-S500BG0EA : 04975769460043 CL-S500BG2EA : 04975769462689
CL-S500BG0KA : 04975769460050

Trademark: **JVC**

Description: Medical Electrical Equipment:
54cm (21.3") Color LCD Monitor

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

Accessory: Single stand power cord, DVI cable, DisplayPort cable, USB cable,
utility disk, installation manual, operation manual
Dual stand power cord x2, DVI cable x2, DisplayPort cable x2,
USB cable x2,
utility disk, installation manual, operation manual,
installation manual for Dualstand

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 electromagnetic compatibility: EN 60601-1-2:2015 / Class B
common specifications: safety: EN 60601-1:2006 + A1:2013 + A12:2014
others: EN 62366:2008; EN 60601-1-6:2010 + A1:2015; EN 62304:2006

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

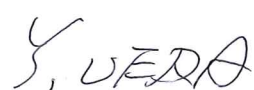
harmonised standards: EN IEC 63000:2018

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: —

Signed for and on behalf of JVCKENWOOD Corporation:

Yokohama, October 22, 2021
Place, date of issue (MM/DD/YYYY)

Signature: 

Yorinobu Ueda
Manager
Quality Assurance Department
Healthcare Business Division
JVCKENWOOD Corporation