



NDS Surgical Imaging  
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EC Declaration of Conformity  
Dossier No. CE-SC-001

PRODUCT DESCRIPTION

1. Product Name: Radiance 26 inch Flat-Panel Display
2. Model Number: SC-WU26-wxyzz, where w may be A, L, R, S, M or N; x may be 0-9, A or B; y may be 1-9 or A and zz may be 00-16.
3. Classification: Class I per Annex IX, Rule 12 of the Council Directive 93/42/EEC include amending directive 2007/47/EC
4. Safety Standards: The Radiance 26-inch Flat-Panel Display is tested to meet the medical safety requirements of IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1, and the Medical Device Directive, 93/42/EEC.
5. Intended use: The Radiance display is a Class I medical device intended for use in a medical environment to display high quality video and graphic images.

NDS QUALITY SYSTEM ASSESSMENT

6. Certification Body: AB Certification (France) Registration Number: A539
7. Conformity Route: NDS Surgical Imaging, LLC, has established a full quality system in accordance with ISO 9001:2008, ISO 13485:2003 and the Medical Device Directive, Annex VII. FDA Registration #2954921 and #1226517

The management of NDS Surgical Imaging, LLC, declares that the devices described above are in compliance with the following directives, standards and normative documents. NDS Surgical Imaging TUV Certificate number is CU 72090341 and CB certificate and report (US-TUVR-4823-A3)

- Council Directive 93/42/EEC and 2004/108/EEC include amending directive 2007/47/EC
- EN 60601-1-2:2001 +A1:2006

Under 93/42/EEC

- In accordance with EN 60601-1-2:2001 +A1:2006, Emission
  - CISPR 11:1998 +A1:1999 + A2:2002 Radiated & Conducted Emissions
- In accordance with EN 60601-1-2:2001 +A1:2006, Immunity with modification:
  - EN 61000-3-2: Harmonics
  - EN 61000-3-3: Flicker
  - EN 61000-4-2: Electrostatic Discharge
  - EN 61000-4-3: Radiated Immunity
  - EN 61000-4-4: Transients
  - EN 61000-4-5: Surges Line to Line
  - EN 61000-4-6: Conducted Immunity
  - EN 61000-4-8: Magnetic Immunity
  - EN 61000-4-11: Voltage Variations & Interruptions

Technical documentation for conformity assessment of the aforementioned device is maintained on file at the following location: NDS Surgical Imaging, 5750 Hellyer Ave., San Jose, CA 95138, U.S.A

Signed:

Name: Chad Chang

Function: Vice President of Engineering

Date: 2010-07-12

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