

EC Declaration of Conformity
Dossier No. CE-SC-001

PRODUCT DESCRIPTION

1. Product Name: Radiance 19, 24, 26, 27, 32, 42 and 55" inch Flat-Panel Displays
2. Model Number: SC-WUxx-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 00-23.
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 series Flat-Panel Display is tested to meet the medical safety requirements of IEC 60601-1:2005 3rd edition, ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, and the Medical Device Directive, 93/42/EEC and 2007/47/EC.
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: Intertek Certification Number: 0019394-00 and, 0019396-00
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

The management of NDS Surgical Imaging, LLC, declares that the devices described above are in compliance with the following directives, standards and normative documents.

- Council Directive 93/42/EEC and 2004/108/EEC include directive 2007/47/EC
- EN 60601-1-2:2001 +A1:2006
- Council Directive 2011/65/EU (also known as "RoHS Recast"). F-21-005, 75B0101

Under 93/42/EEC

- In accordance with EN 60601-1-2:2007
 - CISPR 11:1998 +A1:1999 + A2:2002 Radiated & Conducted Emissions
 - 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: Chad Chang
Name: Chad Chang

Function: Chief Technology Officer
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