NDS SURGICAL · IMAGING

NDS Surgical Imaging
5750 Hellyer Ave
San Jose, CA 95138
Tel: 408-776-0085
Fax: 408-776-9878

EC REP
GSI Distribution GmbH
Münchner Strasse 2A
82152 Planegg
Germany
Tel: +49 89 31 707 100
info.gsig-europe@gsig.com

Asia Pacific
East Square Omori
6-29-14, Minamioi,
Shinagawa-ku, Tokyo 140-0013 Japan
Tel: 81-3-5753-2466
info@ndssi.jp

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

### PRODUCT DESCRIPTION

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|---|---|
| 1. Product Name: | EndoVue 15", 19", 21", 24", 32" and 42" inch Flat-Panel Display |
| 2. Model Number: | BC-WU15-wxyzz, BC-WU19-wxyzz, BC-WU21-wxyzz, BC-WU24-wxyzz, BC-WU32-wxyzz and BC-WU42-wxyzz where w may be G, A, L, R, S, M or N; x may be 0-9, A or B; y may be 0-9 or A and zz may be 00-19. |
| 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 EndoVue 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 EndoVue 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

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|---|---|---|---|
| 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. NDS Surgical Imaging has TUV Certificates and CB certificates and reports.

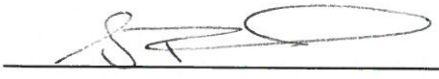
- Council Directive 93/42/EEC and 2004/108/EEC include directive 2007/47/EC;
- EN 60601-1-2: 2007
- Council Directive 2011/65/EU (also known as "RoHS Recast"). F-21-005, 75B0101

Under 93/42/EEC

- In accordance with EN 60601-1-2:2007, Emission
  - CISPR 11: 2004 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:  Function: Senior Director of RA/QA

Name: Shala Famil Date: 08/15/2016