

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.: 80020236 Version: A

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Welch Allyn, Inc.

Business address: 4341 State Street Road
Skaneateles Falls, NY 13153-0220
U.S.A.

Product name: GS Lights



DEVICES:
44416, 44456, 44606, 44616, 44906, 44900-C, 44900-W, 48816

ACCESSORIES:
44215, 48200, 48605, 48805, 48850, 48950, 48955, 48960, 52630, 52640-B,
405966

Classification: I

GMDN code and term: 12276 – Light, examination

Scope of application: All

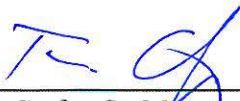
Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.: 80020236 Version: A

| | | | |
|--------------------|-------------------------------|------|--|
| Standards applied: | EN 14971 | 2007 | Medical Devices- Application of Risk Assessment to medical devices |
| | EN 60601-1 (incl. Amendments) | 1990 | Medical Electrical Equipment- part 1: General requirements for basic safety and essential requirements |
| | EN 60601-1-1 | 2000 | Medical Electrical Equipment- part 1-1-General requirements for safety- Collateral Standard: Safety requirements for Medical Electrical Equipment |
| | EN 60601-1-2 | 2004 | Medical Electrical Equipment- part 1-2- General requirements for safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Test |
| | EN 60601-1-4 | 1997 | Medical Electrical Equipment- part 1-4- General requirements for safety- Collateral Standard: General requirements for programmable electrical medical systems |
| | EN 60601-1-6 | 2004 | Medical Electrical Equipment- part 1-6- General requirements for safety- Collateral Standard: Usability |
| | EN 1041 | 2008 | Information supplied by the manufacturer with Medical devices |
| | EN 980 | 2008 | Graphical symbols for use in the labeling of medical devices |
| | EN 62366 | 2008 | Medical devices- Application of usability engineering to medical devices |
| | ISO 14155 | 2003 | Clinical investigation of medical devices for human subjects |
| | ISO 10993-1 | 2003 | Biological evaluation of medical devices -- Part 1: Evaluation and testing |

Authorised Signatory:



Tim Croft Sr. Manager, Regulatory Affairs - JAPAC

2015-09-21

Date

Rydalmere, NSW

Place of Issue

This authorisation is given in the signatory's capacity as representative of the "Manufacturer" (as recorded on page 1 of this declaration)