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

SAP DIR No.: 80020831     Version:     B

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:                Illuminator

REF

901025 ILLUMINATOR, HAND HELD
901000 ACCESSORY/COMPONENT

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.

Standards applied:

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<tr>
<th>Standard</th>
<th>Year</th>
<th>Description</th>
</tr>
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<tr>
<td>ISO 14971</td>
<td>2009</td>
<td>Medical Devices- Application of Risk Assessment to medical devices</td>
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<tr>
<td>ISO 13485</td>
<td>2003</td>
<td>Medical devices - Quality management systems - Requirements for regulatory purposes</td>
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<tr>
<td>IEC 60601-1 (incl. Amendments)</td>
<td>1990</td>
<td>Medical Electrical Equipment- part 1: General requirements for basic safety and essential requirements</td>
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<td>IEC 60601-1-1</td>
<td>2000</td>
<td>Medical Electrical Equipment- part 1-1-General requirements for safety- Collateral Standard: Safety requirements for Medical Electrical Equipment</td>
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<tr>
<td>IEC 60601-1-2</td>
<td>2004</td>
<td>Medical Electrical Equipment- part 1-2- General requirements for safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Test</td>
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<tr>
<td>IEC 60601-1-6</td>
<td>2004</td>
<td>Medical Electrical Equipment- part 1-6- General requirements for safety- Collateral Standard: Usability</td>
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<tr>
<td>EN 62366</td>
<td>2008</td>
<td>Medical devices- Application of usability engineering to medical devices</td>
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Standards applied:

ISO 10993-1  2003  Biological evaluation of medical devices- Part 1:
Evaluation and testing

EN 980  2008  Symbols for use in the labelling of medical devices

EN 1041  2008  Information supplied by the manufacturer of medical devices

Authorised Signatory:

Joshua Kim  Sr. Manager, Regulatory Affairs  Skaneateles Falls, NY USA

Date  Place of Issue

2016-08-10

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