MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

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

Medical device(s): Digital Macro View Otoscope
REF: 901021 Otoscope, Wideview

Standard Otoscope
REF: 901079 Otoscope, Standard

Pocket Otoscope
REF: 901080 Otoscope, Pocket

Accessories
REF: 901001 Accessory Eye, Ear, Nose and Throat

Classification: Class I

GMDN code and term: 12849 – Otoscope, Direct

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.

Full quality assurance procedures certificate: 314505 MP2012

<table>
<thead>
<tr>
<th>Standards applied</th>
<th>Standard</th>
<th>Version</th>
<th>Title</th>
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<tbody>
<tr>
<td>EN ISO/ISO 14971</td>
<td>2012/2ED 2007 CORRECTED</td>
<td>Medical Devices - Application of Risk Management to Medical Devices</td>
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<td>Standard</td>
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<td>Macroview: CAN/CSA C22.2 60601-1-4-2</td>
<td>2000</td>
<td>Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable Electrical Medical Systems adopted IEC 60601-1-4 (00)</td>
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<tr>
<td>Standard and Pocket: EN/IEC 62366</td>
<td>2008/2007</td>
<td>Medical Devices – Application of Usability Engineering to Medical Devices</td>
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**Authorised signatory:**

Joshua Kim  
Senior Manager, Regulatory Affairs
<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
<th>Author</th>
<th>Date</th>
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<tbody>
<tr>
<td>A</td>
<td>Copied Model(s) and Standards Applied from DIR 80016526, Ver. D</td>
<td>M. Pellenz</td>
<td>2013-10-08</td>
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<tr>
<td>B</td>
<td>Updated to Format requested by Australian RA SME; removed 901021 (RPI), 901079 (RPI)</td>
<td>M. Pellenz</td>
<td>2013-10-11</td>
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</table>
| C       | Added RPI-REF; added Pocket LED catalog numbers  
Updated Standards to add 62366 & 10993-1                                                                                                           | Megan Pellenz  | 2014-11-03  |
| D       | Removed any codes not supplied in Australia; separated accessories from devices. Added full list of standards from ASL.                                                                                 | A. Yong / T. Croft | 2014-11-25  |
| E       | Moved 21111 to "Devices" List; Removed Ear Specula 22100, 24302-U, 24303-U, 24304-U, 24305-U, 24320, 24323, 24325, 24330, 24330-B, 24400-U, 52133-B, 52134-B, 52135-B & 52700 to their own DoC as they have a unique/different GMDN. | M. Pellenz     | 2016-02-26  |
| F       | Updated section: removed “Accessories 21501, 21504, 22009, 22120, 23557, 23804, 23857” – they will be listed on separate DoC’s; removed the phrase “Devices:” added 23920; Updated Authorised Signatory section. | M. Pellenz     | 2016-08-04  |
| G       | Updated format. Combined data from DoCs 80016875 Ver F, 80016536 Ver K, and 80017158 Ver K to create one DoC for Australia                                                                                 | B. Rice        | 2018-10-30  |