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 U.S.A.

Medical device(s): RetinaVue Network Software
REF: 901108 PACS Medical Image System

Classification: I

GMDN code and term: 36239 Picture archiving and communication systems

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.

Certificate number for the product quality assurance procedures: EC-certificate No. 314505 MP2012 (Unique ID 170660533)

Standards applied:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Version</th>
<th>Title</th>
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<tbody>
<tr>
<td>EN ISO 14971</td>
<td>2012</td>
<td>Medical devices - application of risk management to medical devices</td>
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<tr>
<td>IEC 62366-1</td>
<td>2015</td>
<td>Medical Devices – Part 1: Application of Usability Engineering to Medical Devices</td>
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<td>IEC 62304</td>
<td>2006</td>
<td>Medical Device Software – Software Life Cycle Processes</td>
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<tr>
<td>NEMA PS 3.1 - 3.20</td>
<td>2016</td>
<td>Digital Imaging and Communications in Medicine (DICOM) Set</td>
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<td>EN 1041</td>
<td>2008</td>
<td>Information Supplied by the Manufacturer of Medical Devices</td>
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Authorised signatory:

Joshua Kim
Senior Manager, Regulatory Affairs

Date: 2018. 05. 25