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): Ear Wash System
REF: 901032 Ear Wash System

Classification: Class I

GMDN code and term: 46323 – Ear canal lavage system

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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EN ISO 14971</td>
<td>2012/2ED 2007 CORRECTED</td>
<td>Medical Devices - Application of Risk Management To Medical Devices</td>
</tr>
</tbody>
</table>

Authorised signatory:

Joshua Kim
Senior Manager, Regulatory Affairs

Date