

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

SAP DIR No.: 80021358      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  
U.S.A.

Product name: EAR SPECULA for use with Welch Allyn Otoscopes

**REF**

901001 ACCESSORY, EYE, EAR, NOSE & THROAT

**#**

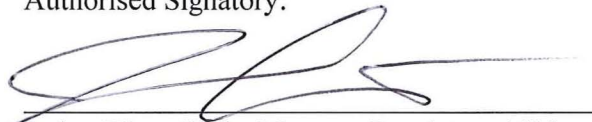
22002, 22003, 22004, 22009, 22023, 22025, 22100, 22120, 24302-U,  
24303-U, 24304-U, 24305-U, 24320, 24320-B, 24323, 24325, 24327,  
24330, 24330-B, 24400-U, 52133, 52134, 52135, 52432-U, 52434-U,  
52700, 52432-UB, 52434-UB.

Classification: I  
GMDN code and term: 35348 – Speculum, ear  
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: EN ISO 10993-1      2009 + Corr      Biological evaluation of medical devices - Part 1:  
2010      Evaluation and testing within a risk management  
process

Authorised Signatory:

  
Joshua Kim    Senior Manager, Regulatory Affairs

2016-08-10  
Date

Skaneateles Falls, NY USA  
Place of Issue

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