Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

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 2010	Biological evaluation of medical devices - Part 1: 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)