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 tips 901001 Accessory, EENT REF: 29360, 293600
Classification:	Class I
GMDN code and term:	31940 – Ear phone cushion
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 MP2016

Standards applied:	**Standard**	**Version**	**Title**
	EN ISO/ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 14971	2012/2ED 2007 CORRECTED	Medical Devices - Application of Risk Management To Medical Devices
	EN ISO 10993-1	2009 + Corr 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Authorised signatory:

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2021-04-28
Date