

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

Standards applied:

Standard	Version	Title
EN ISO/ISO 13485	2012/2ED 2003	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	1998	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

Authorised signatory:

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Date