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): Digital Macro View Otoscope
REF: 901021 Otoscope, Wideview

Standard Otoscope
REF: 901079 Otoscope, Standard

Pocket Otoscope
REF: 901080 Otoscope, Pocket

Accessories
REF: 901001 Accessory Eye, Ear, Nose and Throat

Classification: Class I

GMDN code and term: 12849 – Otoscope, Direct

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/ISO 14971	2012/2ED 2007 CORRECTED	Medical Devices - Application of Risk Management to Medical Devices
EN/IEC 60601-1	2006/ 2005+A1	Medical Electrical Equipment - Part 1: General Requirements for Safety
Macroview: CAN/CSA 60601-1-1-2	CAN/CSA 2nd edition IEC 3rd edition	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral Standard Safety requirements for Medical Electrical Systems adopted IEC60601-1 3ed (01)
EN/IEC 60601-1-2	4ED 2014-02-25	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard:

Standards applied:

Standard	Version	Title
		Electromagnetic Compatibility - Requirements and Tests
Macroview: CAN/CSA C22.2 60601-1-4-2	2000	Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable Electrical Medical Systems adopted IEC 60601-1-4 (00)
EN/IEC 60601-1-6	2010/3ED 2010	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability
Macroview: IEC 60601-1-6	2004	Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability
Standard and Pocket: EN/IEC 62366	2008/2007	Medical Devices – Application of Usability Engineering 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:

Joshua Kim
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2019.03.07
Date