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): Anoscope, single use and accessories
DEVICES:
53110, 53110-B

ACCESSORIES:
30200, 30210, 36019, 73226

Classification: I

GMDN code and term: 44914 - Anoscope, single-use

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:

Standard	Version	Title
IEC 60601-1	2005+A1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2	2014	Medical Electrical Equipment - Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6	2010	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 60601-2-18	2009	Medical electrical equipment Part 2: Particular Requirements for the basic safety and essential performance of endoscopic equipment
EN ISO 10993-1	2009 COR 2010	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

Standards applied:

Standard	Version	Title
EN ISO 13485	2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971	2012	Medical Devices – Application of risk management to medical devices
EN ISO 62366-1	2015	Application of usability engineering to medical devices
EN 1041	2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1	2016	Medical devices_- Symbols to be used with medical device labels, labelling and information to be supplied_- Part_1: General requirements

Authorised signatory:

Joshua Kim
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2018·10·30
Date

Document Change History

Version	Description	Author	Date
A	Initial release		
B	Updated to new format and new safety agency reports	Killoran	2018-10-30