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, USA
Medical device(s):	Welch Allyn 9600 Plus Calibration Tester & Calibration Keys RPI 901121 Accessory, Thermometry
Classification:	Class I
GMDN code and term:	36871 Test Instrument, Thermometer
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
EN 50581	2012	Technical documentation for the assessment of electrical and electronic products with the restriction of hazardous substances.
EN/IEC 61010-1	2010 (3rd Ed.)	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements. (Note: applied to 01802-110)
EN 61326	A2:2001	Radiated & Conducted Emissions
FCC 15.109(g) (CISPR 22:1997)	Class B: 2003	ANSI C63.4:2001 Radiated Emissions
FCC 15.107	Class B: 2003	ANSI C63.4:2001 Conducted Emissions
EN 61000-3-2	2000	Current Harmonics
EN 61000-3-3	2001	Voltage Fluctuations

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Date

Document Change History

Version	Description	Author	Date
A	Initial release	S. Stearns	2018-11-1