Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.:	80016543	Version:	D

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.
Product name:	Flexiport EcoCuff
#	All product codes with the prefix ECOCUFF-
Classification:	I
GMDN code and term:	34978 – Cuff, Blood Pressure, reusable
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:			
	ISO 10993-1	2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
	IEC 62366	2007	Medical Devices – application of Usability Engineering to Medical Devices
	AAMI / ANSI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003	R2008	Manual, Electronic, or Automated Sphygmomanometers
	ISTA 2A	2008	Packaged-Products 150 LB (68 KG) or Less
	EN 1060-1	2009	Non-invasive Sphygmomanometers – Part 1: General Requirements
	EN 1060-2	2009	Non-invasive Sphygmomanomters – Part 2: Supplementary Requirements for Mechanical Sphygmomanometers
	AAMI/ISO 81060-1	2007	Non Invasive Sphygmomanometers – Part 1: Requirements and Test Methods for Non-automated Measurement Type

Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.:	80016543	Version:	D

	IEC 80601-2-30	2009	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.
	ISO 81060-2	2009	Non Invasive Sphygmomanometers-Part 2: Clinical Validation of Automated Measurement Type
	EN 980	2008	Symbols for Use in the Labelling of Medical Devices
	EN 1041	2008	Information Supplied by the Manufacturer of Medical Devices
	ISO 14971	2007	Medical Devices – Application of Risk management to Medical Devices
	EN ISO 13485	2003 COR1:2009	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Authorised Signatory:

Tim Croft Sr. Manager, Regulatory Affairs - JAPAC Date

Rydalmere, NSW
Place of Issue

This authorisation is given in the signatory's capacity as representative of the "Manufacturer" (as recorded on page 1 of this declaration)

Welch Allyn Australia (Pty) Ltd.
Unit 5, 38 – 46 South Street
Rydalmere NSW 2116

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.:	80016543	Version:	D

Document Change History

Version	Description	Author	Date
A	Initial Release	Not recorded	2010/12/13
B	Added ECO-MLT	Not recorded	2012/12/07
C	Added new part numbers. ECOCUFF-09, ECOCUFF -10, ECOCUFF-11, ECOCUFF-12, ECOCUFF-MLT	Not recorded	2013/05/13
D	Updated to new format	Tim Croft	2015-04-27