MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 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 CP150 Electrocardiograph
901049 Electrocardiograph
901051 Spirometer

Classification: IIa

GMDN code and term: 16231 – Interpretive multichannel electrocardiograph

Scope of application: All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate: 314505 MR2

Standards applied:

Standard	Version	Title
AAMI EC-11	1991 (R2007)	Diagnostic electrocardiographic devices
AAMI EC-53	1995 (R2008)	ECG cables and leadwires
EN 1041	2008 +A1:2013	Information supplied by the manufacturer with medical devices
EN/IEC 60601-1	2nd and 3rd Edition	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN/IEC 60601-1-4	1996/1996 +A1:1999	Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: General Requirements for Programmable Electrical Medical Systems
EN/IEC 60601-1-6	2010 (3rd Ed)	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
EN/IEC 62366	2008/2007	Medical devices – Application of Usability Engineering to Medical Devices
IEC/EN60601-2-25	Edition (1.0	Medical electrical equipment - Part 2-25:

Standards applied:

Standard	Version	Title
	and 2.0)	Particular requirements for the basic safety and essential performance of electrocardiographs
IEC/EN60601-2-51	2003	Particular Requirements For Safety, Including Essential Performance, Of Recording And Analysing Single Channel And Multichannel Electrocardiographs
EN/ISO 14971	2007 Second Edition. 2012	Medical Devices – Application of Risk Management to Medical Devices
EN 62304	2006/AC:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1	2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN/ISO 10993-5	2009/2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN/ISO 10993-10	2010/ 2010	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Delayed-Type Hypersensitivity
CISPR 11/EN 55011	2009/2009 +A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement
EN/IEC 60601-1-2	2007/2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN/IEC 61000-3-2	2006/2005 +A1:2009/ 2008 +A2:2009/ 2009	Electromagnetic Compatibility (EMC) - Part 3-2: Limits - Limits For Harmonic Current Emissions (Equipment Input Current Up To and Including 16 A Per Phase)
EN/IEC 61000-3-3	2008/2008	Electromagnetic Compatibility (EMC) - Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, For Equipment With Rated Current <= 16 A Per Phase and Not Subject to Conditional Connection
EN/IEC 61000-4-2	2009/2008	Electromagnetic Compatibility (EMC) -- Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
EN/IEC 61000-4-3	2006/2006 +A1:2008/ 2007 +A2 2010/ 2010	Electromagnetic Compatibility (EMC) -- Part 4-3: Testing and Measurement Techniques - Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
EN/IEC 61000-4-4	2004/2004 +A1:2010/	Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques -

Standards applied:

Standard	Version	Title
	2010	Electrical fast transient/burst immunity test
EN/IEC 61000-4-5	2006/2005	Electromagnetic Compatibility (EMC) -- Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
EN/IEC 61000-4-6	2009/2008	Electromagnetic Compatibility (EMC) -- Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields
EN/IEC 61000-4-8	2010/2009	Electromagnetic Compatibility (EMC) -- Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
EN/IEC 61000-4-11	2004/2004	Electromagnetic compatibility (EMC) -- Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
ISTA 2A	2011	Packaged-Products 150 lb (68 kg) or Less
EN ISO 26782	2009/ AC:2009	Anesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
NEMA/MITA DICOM	2014	DICOM
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

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Date

Document Change History

Version	Description	Author	Date
E	New template, updated reference standard 1041 added A1:2013	Rob Berry	2018-07-02