


MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
DECLARATION OF CONFORMITY PROCEDURES

SAP DIR No.: 80020493 Version: C

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 U.S.A.
Product name:	Mobile Stand
	2400-MS, 7000-MS3, 7670-12
Classification:	I
GMDN code and term:	30110 – Stand
Scope of application:	All

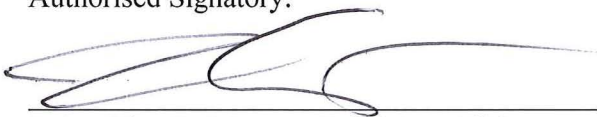
Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

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Standards applied:	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
	ANSI/AAMI EN60601-1:2005	2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD.)
	EN 60601-1	2006 – 3 rd Edition	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	IEC 60601-1	2005 – 3 rd Edition	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	EN 60601-1	1990 + A1: 1992 + A2: 1995	Medical Electrical Equipment Part 1: General Requirements for Safety
	IEC 60601-1	1988 + A1: 1991 + A2: 1995	Medical Electrical Equipment Part 1: General Requirements for Safety
	UL 60601-1	First Edition, 2003	Medical Electrical Equipment Part 1: General Requirements for Safety

Authorised Signatory:



Joshua Kim, Sr. Manager, Regulatory Affairs

2016.08.10

Date

Skaneateles Falls, NY

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)