Welch Allyn DECLARATION OF CONFORMITY

SAP DIR No.: 80016302 Version: A

We declare, under our sole responsibility, that the product listed below conforms to the provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
EC REP	Regulatory Affairs Representative Welch Allyn, Ltd. Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	ProBP 3400 Series
Model(s):	34BFHT-B, 34XFHT-B, 34BXHT-B, 34XXHT-B, 34BFWT-B, 34XFWT-B, 34BXWT-B, 34XXWT-B, 34BFST-B, 34XFST-B, 34BXST-B, 34XXST-B, 34BFHT-2, 34XFHT-2, 34BXHT-2, 34XXHT-2, 34BFWT-2, 34XFWT-2, 34BXWT-2, 34XXWT-2, 34BFST-2, 34XFST-2, 34BXST-2, 34XXST-2, 34BFHT-4, 34XFHT-4, 34BXHT-4, 34XXHT-4, 34BFWT-4, 34XFWT-4, 34BXWT-4, 34XXWT-4, 34BFST-4, 34XFST-4, 34BXST-4, 34XXST-4, 34BFHT-6, 34XFHT-6, 34BXHT-6, 34XXHT-6, 34BFWT-6, 34XFWT-6, 34BXWT-6, 34XXWT-6, 34BFST-6, 34XFST-6, 34BXST-6, 34XXST-6, 34BFHT-C, 34XFHT-C, 34BXHT-C, 34XXHT-C, 34BFWT-C, 34XFWT-C, 34BXWT-C, 34XXWT-C, 34BFST-C, 34XFST-C, 34BXST-C, 34XXST-C, 34BFHT-7, 34XFHT-7, 34BXHT-7, 34XXHT-7, 34BFWT-7, 34XFWT-7, 34BXWT-7, 34XXWT-7, 34BFST-7, 34XFST-7, 34BXST-7, 34XXST-7
Annex:	II of MDD 93/42/EEC
Classification:	IIa
Classification Rules:	10
GMDN Code and Term:	16173 – Sphygmomanometer, electronic, automatic
UMDNS Code and Term	16173 - Electronic sphygmomanometers designed with a self-contained program for proper function and automatic cuff inflation and measurement cycles. These instruments usually display current heart rate and mean arterial pressures in addition to systolic and diastolic blood pressure. Most automatic electronic sphygmomanometers will sound an alarm if blood pressure exceeds preset limits, and some can be set to take readings continuously. Although these instruments are not intended for monitoring for recording purposes, they may include a printer and keep a record of several measurements.
Notified Body:	DQS Medizinprodukte GmbH, (CE 0297) August-Schanz-Str.21, 60433 Frankfurt am Main certificate 314505 MR2
Quality Sys. Certificate	Certificate 314505 MP27 indicating conformance to DIN EN ISO 13485:2003.
Standards	EN 980: 2008 Symbols for use in the labeling of medical devices

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Applied:	EN 1041:2008	Information supplied by the manufacturer with medical devices
	EN 1060-1: 1995	Non-invasive sphygmomanometers - Part 1: General requirements
	EN 1060-3: 1997	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electromechanical blood pressure measuring systems
	EN ISO 10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing
	EN ISO 13485: 2003	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971: 2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
	EN60601-1: 1990, 2nd Edition; +A1:1991 +A2:1995	Medical Electrical Equipment, Part 1: General Requirements for Safety.
	EN60601-1-2: 2007	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	EN 60601-1-4: 1996	Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
	EN 62366: 2008	Medical devices - Application of usability engineering to medical devices
	AAMI SP10: 2002 + A1: 2003	Manual, electronic, or automated sphygmomanometers

Authorised Signatory:

Fred Schweitzer, Regulatory Affairs Representative

2010-10-29
Date