

# Welch Allyn® DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016302

Version: F

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

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 Limited  
Navan Business Park  
Dublin Road  
Navan, County Meath  
Republic of Ireland

Product Name: ProBP 3400 Series

**REF** 901055, DIGITAL BLOOD PRESSURE DEVICE

**#** 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

Medical Device Conformity Assessment Route Annex: II

Medical Device Classification: IIa

Medical Device Classification Rules: 10

GMDN Code and Term: 45617 – Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

UMDNS Code and Term: 16173 - Electronic sphygmomanometers designed with a self-contained program for proper function and automatic cuff inflation and measurement cycles.

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Notified Body: DQS Medizinprodukte GmbH,  
(CE 0297) August-Schanz-Str.21, 60433 Frankfurt am Main  
EC-certificate No. 314505 MR2.

Standards Applied:	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	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
	EN60601-1: 1990, 2 <sup>nd</sup> 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:



Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}



Date

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Place of Issue