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: (CE 0297)	DQS Medizinprodukte GmbH, 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, 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:

Fiona Butler — 2016-06-24 — Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue