Hillrom

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

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, and
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment, and
- 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 as amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS3).

Document Number 80016302	Version J	
Product Name	ProBP 3400 Series	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificates Declaration of Conformity Validity	EC Certificate 314505 MR2 Expiry Date: 2024-05-26	
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan Co. Meath C15 AW22 Ireland	SRN: IE-AR-000000768

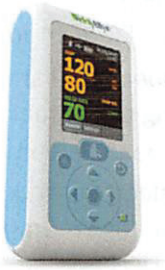
REF #

34BFHT-B	34XFHT-B	34BXHT-B	34XXHT-B	34XXHT-B
34XFST-B	34BXST-B	34XXST-B	34BFHT-2	34XFHT-2
34BXWT-2	34XXWT-2	34BFST-2	34XFST-2	34BXST-2
34XXHT-4	34BFWT-4	34XFWT-4	34BXWT-4	34XXWT-4

34XFWT-B	34BXWT-B	34XXWT-B	34BFST-B
34BXHT-2	34XXHT-2	34BFWT-2	34XFWT-2
34XXST-2	34BFHT-4	34XFHT-4	34BXHT-4
34BFST-4	34XFST-4	34BXST-4	34XXST-4

901055, DIGITAL BLOOD PRESSURE DEVICE

Radio equipment	Laird Tech, Model BTM411

Object of the declaration	
Accessories and components	See Appendix A
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIa
Medical Device Classification Rule	10
Standards	See Appendix A
GMDN Code and Term	45617 – Automatic-inflation electronic sphygmomanometer, portable, arm/wrist
UMDNS Code and Term	16173 - Sphygmomanometers, Electronic, Automatic
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

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Authorised Signatory

Joshua Kim
Senior Manager
Global Regulatory Affairs

2021. 11. 15
Date

Skaneateles Falls NY, USA
Place of Issue

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN 60601-1	2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2	2015	Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	EN ISO 81060-1	2012	Non-Invasive Sphygmomanometers - Part 1: Requirements and Test Methods for Non-Automated Measurement Type
	EN ISO 81060-2	2013	Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type
	EN 80601-2-30	2018	Medical Electrical Equipment - Part 2-30: Particular Requirements for The Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers
	EN 62366-1	2015	Medical devices -- Part 1: Application of usability engineering to medical devices
	EN ISO 13485	2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 10993-1	2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
	EN 62474	2012	Material declaration for products of and for the electrotechnical industry
	EN 62304	2015	Medical Device Software - Software Life Cycle Processes
	EN 62353	2008	Medical Electrical Equipment - Recurrent Test and Test After Repair of Medical Electrical Equipment
	EN 62321-1	2013	Determination of certain substances in electrotechnical products – Part 1: Introduction and overview
Directive 2014/53/EU	EN 62311	2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz)

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Standards Applied	Number	Version/Date of Issue	Title
	EN 301 489-1	2019-03	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
	EN 301 489-17	2017-03	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
	EN 300 328	2016-11	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of Directive 2014/53/EU
	EN 301 893	2017-0	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances