



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

### DECLARATION OF CONFORMITY

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA
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I, Lori Burns, hereby declare that the below mentioned medical device

- (i) complies with all the requirements under the Act;
- (ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and
- (iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name:	Vital Signs Monitor Core
Specified name:	Welch Allyn® Connex Spot Monitor
Brand/model:	Welch Allyn®
Manufacturer:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA
Manufacturing Site:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA
Country of origin:	USA
Risk-based Classification:	Class B
Classification Rule:	10 (i)
GMDN code	57960 – Multiple physiological parameter spot-check analysis system, clinical
Medical device registration number or any approval code:	510(k): K142356 EC Cert: 314505 MR2



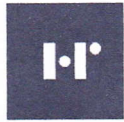
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(B) Quality Management System Certificate:

Certification Body: DQS Medizinprodukte GmbH  
Certificate Number: 314505 MP2016  
Issue Date: 2019-12-09  
Expiry Date: 2022-12-08  
QMS Standard: EN ISO 13485:2016

**Standards Applied:**

Number	Title
EN 50581 <sup>3</sup>	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN/IEC 62304	Medical Device Software – Software Life Cycle Processes
EN/ISO 1060-3	Non-Invasive Sphygmomanometers – Part 3. Supplementary Requirements for Electro-Mechanical Blood Pressure Measuring Systems
EN/IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN/IEC 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN/IEC 62366-1	Medical devices – Application of Usability Engineering to Medical Devices
EN/IEC 60601-1-6	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
EN/IEC 60601-1-8	Medical Electrical Equipment – Part 1-8: General Requirements for Safety – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
EN/ISO 60601-2-49	Medical electrical equipment_ - Part_2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN/ISO 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN/ISO 80601-2-56	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN/ISO 80601-2-61	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 62133-2	Medical Electrical equipment - Part 1-8: General requirements for basic safety and essential performance- Collateral Standard: General Requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.



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EN ISO 10993-1	Biological evaluation of medical devices_ - Part_1: Evaluation and testing within a risk management process
EN ISO 15223-1	Medical devices_ - Symbols to be used with medical device labels, labelling and information to be supplied_ - Part_1: General requirements
EN 1041+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971	Medical devices_ - Application of risk management to medical devices
EN 50419	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from: 01 July 2020

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

Lori Burns  
Director, Regulatory Affairs

2020-07-01

Date:



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**Document Change History**

Version	Description	Author	Date
A	Abandoned (not used)	H. Doung	2018-01-18
B	New release	S. Stearns	2020-07-01