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

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[3]	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:

Document Change History

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