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	DIR 80018378, Version M	
Product Name	Connex® Vital Signs Monitor 6000 Series	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-00013394
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

The Connex® Vital Signs Monitor 6000 Series part number structure is in the format of 6#XXXX-Z where each character has pre-allocated values:

- First two digits are a model # series
  (67) = Standard, Includes nurse call, Ethernet, USB connectivity and optional radio, **(68)** = Wireless. Includes all standard features plus an internal 802.11 a/b/g radio.

- The next 5 characters designate installed parameters:

Model	Parameter				Power
67 = Standard	N = Nellcor	C = CO2	T = SureTemp	P = Printer	(examples, not all-inclusive)
68 = Wireless	M = Masimo	R = RRA	E = Braun	X = None	B = North America 2 = Europe 4 = United Kingdom 6 = Australia/New Zealand 7 = South Africa
	H = Hemoglobin/ Masimo	S = ES	X = None		
	X = None	F = ES Safety			

An X in a position designated feature not installed and a blank panel covers that position. Following the dash is either a single or double character where Z is for the Power Cord type which may be any alpha-numeric including 0-9 and A-Z.

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#	901060 Vital Signs Monitor
Radio equipment	Laird: 802.11 a/b/g/n Enterprise Wi-Fi + Bluetooth Communications Subsystem
Object of the declaration	 Connex® Vital Signs Monitor 6000 Series
Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	IIb
Medical Device Classification Rule	10
Standards	See Appendix A
GMDN Code and Term	33586 - General-purpose multi-parameter bedside monitor
UMDNS Code and Term	20172 - Monitors, Physiologic, Multipurpose, Bedside, Configured
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Authorised Signatory

Megan Pellenz

Megan Pellenz
Sr. Manager, Regulatory Affairs

2024-01-23
Date

Skaneateles Falls NY, USA
Place of Issue

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Appendix A: Standards and Common Specifications

Standards Applied	Number	Title
Directive 93/42/EEC	EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
	EN 60601-1-6	Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
	EN 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 60601-2-27	Medical Electrical Equipment- Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
	EN 60601-2-49	Medical Electrical Equipment – Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment
	EN ISO 13485	Medical Devices Quality Management Systems – Requirements for regulatory purposes
	EN 80601-2-30	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
	EN ISO 80601-2-55	Medical Electrical Equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
	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. Particular requirements for basic safety and essential performance of pulse oximeter equipment
	EN 62304	Medical Device Software – Software Life Cycle Processes
	EN 62366-1	Medical devices – Application of Usability Engineering to Medical Devices
	ISO 10993-10	Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
	ISO 10993-5	Biological evaluation of medical devices- Part 5: Test for in-vitro cytotoxicity

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Standards Applied	Number	Title
	ISO 10993-1	Biological evaluation of medical device- Part 1: Evaluation and testing within a risk management process
	EN ISO 14155	Clinical investigation of medical devices for human subjects- good clinical practices
	EN ISO 81060-2	Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type
	EN ISO 80369-5	Small bore connectors for liquids and gases in healthcare applications –Part 5: Connectors for limb cuff inflation applications
Directive 2014/53/EU	EN 301 489-17	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	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	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	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances