Baxter

Welch Allyn, Inc. is a subsidiary of Baxter International, Inc.

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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), and
- Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Text with EEA relevance).

Document Number	DIR 80019030, Version R	
Product Name	Connex® Spot Monitor	
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

2 Digit Number	SpO2	Temperature
71 = Value Series	W = Nonin	E = Braun Pro6000 IR
	X = Blank	T = SureTemp Plus
		X = Blank
73 = BlueTooth	C = Covidien/Nellcor	E = Braun Pro6000 IR
	M = Masimo	T = SureTemp Plus
	R = Masimo SpO2 & RRp	X = Blank
	W = Nonin	
74 = WiFi Ready	C = Covidien/Nellcor	E = Braun Pro6000 IR
	M = Masimo	T = SureTemp Plus
	R = Masimo SpO2 & RRp	X = Blank
	W = Nonin	
75 = WiFi	C = Covidien/Nellcor	E = Braun Pro6000 IR
	M = Masimo	T = SureTemp Plus
	R = Masimo SpO2 & RRp	X = Blank
	W = Nonin	

(Power Cord) depends on region.

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

#	901058 Vital Signs Monitor Core
Radio equipment	Laird WB45NBT 802.11 a/b/g/n Enterprise Wi-Fi + Bluetooth Communications Subsystem WB45NBT is a modularly approved radio under RED, details in DIR 60086189.
Object of the declaration	 Connex Spot Monitor
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	57960 - Multiple physiological parameter spot-check system, clinical
UMDNS Code and Term	25209- Monitor, Physiologic, Vital Signs
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Authorised Signatory

Electronically signed by: JOSEPH OLSAVSKY
Reason: I approve this document
JOSEPH OLSAVSKY Date: Jan 30, 2025 16:44 EST

Joe Olsavsky
Sr. Director, Regulatory Affairs

30-Jan-2025
Date

Skaneateles Falls NY, USA
Place of Issue

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 2: Collateral Standard: Electromagnetic Compatibility: Requirements and Test
	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 ISO 81060-2	Non-invasive sphygmomanometers_- Part_2: Clinical validation of automated measurement type
	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	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
	EN 62366-1	Medical devices -- Part 1: Application of usability engineering to medical devices
	EN 62304	Medical Device Software – Software Life Cycle Processes
	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
	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 ISO 14971	Medical devices_- Application of risk management to medical devices

Standards Applied	**Number**	**Title**
	EN ISO 14155	Clinical investigation of medical devices for human subjects_- Good clinical practice
	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Directive 2014/53/EU	EN 301 489-1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
	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
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