

## 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:

- the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- the 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
- the 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 (RoHS)

Manufacturer's Name and Business Address: Welch Allyn, Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153, USA



Regulatory Affairs Representative  
Welch Allyn Limited  
Navan Business Park  
Dublin Road  
Navan, County Meath  
Republic of Ireland

Product Name<sup>1,3</sup>: Connex® Spot Monitor



<sup>1,3</sup>

901058 Vital Signs Monitor Core



<sup>1,3</sup>

The Connex Spot Monitor comes in four series 71,73, 74 and 75  
7X (SpO2 option) (Temperature option) – (Power Cord)  
SpO2 options: W= Nonin; C= Covidien; M= Masimo; R=Masimo SpO2 and RRp;  
X= No SpO2  
Temperature options: T= SureTemp Plus; E= Braun Pro 6000; X= No Temperature option.  
(Power Cord) depends on region.

Radio equipment<sup>2</sup>: Laird WB45NBT  
(DIR 60086189)

Object of the declaration<sup>2</sup>: 802.11 a/b/g/n Enterprise Wi-Fi + Bluetooth Communications Subsystem

Accessories and components<sup>2</sup>: Not Applicable

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

Medical Device Conformity Assessment Route Annex <sup>1</sup> :	II	
Medical Device Classification <sup>1</sup> :	IIa	
Medical Device Classification Rules <sup>1</sup> :	10	
GMDN Code and Term <sup>1</sup> :	57960 - Multiple physiological parameter spot-check analysis system, clinical	
UMDNS Code and Term <sup>1</sup> :	25209- Monitor, Physiologic, Vital Signs	
Notified Body <sup>1</sup> : (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	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	

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC

<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

