DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80019030 Version: A

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 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity
- 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
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Connex® Spot Monitor
REF	901058 Vital Signs Monitor Core
#	• The Connex Spot Monitor comes in four series 71,73, 74 and 75 71(SpO2 option) (Temperature option) – (Power Cord) SpO2 options: W= Nonin; C= Covidien; M= Masimo; X= No SpO2 Temperature options: T= SureTemp Plus; E= Braun Pro 6000; X= No Temperature option. (Power Cord) depends on region.
Medical Device Conformity Assessment Route Annex:	II
Medical Device Classification:	IIa
Medical Device Classification Rules:	10
GMDN Code and Term:	57960 - Multiple physiological parameter spot-check analysis system, clinical

Welch Allyn®

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UMDNS Code and Term	25209- Monitor, Physiologic, Vital Signs	
Notified Body: (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2	
Standards Applied:	EN 50581	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	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/IEC 60601-2-49	Medical Electrical Equipment – Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment

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IEC 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
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
ISO 80601-2-61	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2015-04-27
Date

Navan
Place of Issue