Welch Allyn® DECLARATION OF CONFORMITY

SAP DIR No.: 80017313 Version: A

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.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Connex Module Accessories
REF	405672 (NIBP) 405701 (SureTemp Thermometer) 405712 (Nellcor SpO2) 408186 (SureTemp Thermometer)
Annex:	II
Classification:	IIa
Classification Rules:	10
GMDN Code and Term:	36551 – Patient monitoring system module, blood pressure, noninvasive 36562 – Patient monitoring system module, temperature 36554 - Patient monitoring system module, pulse oximetry
UMDNS Code and Term	11753 - Noninvasive Blood Pressure (NIBP) Modules, Physiologic 11761 - Temperature Modules, Physiologic Monitor 11763 - Pulse Oximetry Modules, Physiologic Monitor
Notified Body: (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main certificate 314505 MR2.

Standards Applied:	EN 1060-1	Non-invasive sphygmomanometers - Part 1: General requirements
	EN 1060-3	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

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EN 60601-1	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
EN 62304	Medical Device Software – Software Life-Cycle Processes
EN 62366	Medical devices – Application of usability engineering to medical devices
EN 9919	Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use

Authorised Signatory:

Paul G Oris

Paul Oris, Regulatory Affairs Representative

2013-07-25

Date

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Document Change History

Version	Description	Author	Date
A	Initial Release	S. Schmidt	2011-11-02