DECLARATION OF CONFORMITY

SAP DIR No.: 80017313  Version: A


Manufacturer’s Name and 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: Ila
Classification Rules:

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: DQS Medizinprodukte GmbH,
(CE 0297) 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 Oris, Regulatory Affairs Representative

Date:

2013-07-25
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### Document Change History

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