DECLARATION OF CONFORMITY
(based on Singapore’s Form no. DOC-v1/11)

SAP DIR No.: 80018976 Version: A

Name and Address of Product Owner:
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Medical Device(s):
Product Name: Connex® Vital Signs Monitor 6000 Series
Model Number: 901060 Vital Signs Monitor

The Connex® Vital Signs Monitor 6000 Series part number structure is in the format of 6# XXXX-Z where each character has pre-allocated values:

- First two digits are a model # series
  (63 = Basic Com Module, 64 = Standard Com Module, 65 = Standard Com Module with Wireless. Monitors capable of supporting a combination of CO2/RR, RRA, or ES (patient movement) : 67 = Standard, Includes nurse call, Ethernet, USB connectivity and optional radio, 68 = Wireless. Includes all standard features plus an internal 802.11 a/b/g radio.

- The next 5 characters designate installed parameters:

<table>
<thead>
<tr>
<th>Model</th>
<th>Parameter</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>67 = Standard</td>
<td>N = Nellcor</td>
<td>X</td>
</tr>
<tr>
<td>68 = Wireless</td>
<td>M = Masimo</td>
<td>R = RRA</td>
</tr>
<tr>
<td></td>
<td>H = Hemoglobin/Masimo</td>
<td>S = ES</td>
</tr>
<tr>
<td></td>
<td>X = None</td>
<td>F = ES Safety</td>
</tr>
<tr>
<td></td>
<td>X = None</td>
<td>X = None</td>
</tr>
</tbody>
</table>

- An X in a position designated feature not installed and a blank panel covers that position. Following the dash is either a single or double character where Z is for the Power Cord type which may be any alpha-numeric including 0-9 and A-Z.

Manufacturing Site:
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153, USA
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Risk Classification: Class C, rule 10(i)

Quality Management
Certification Body: DQS Medizinprodukte GmbH
Certificate Number: 314505 MP2012
Issue Date: 2013-12-09
Expiry Date: 2016-12-08

Standards Applied:

- EN/ISO 1060-1 Non-Invasive Sphygmomanometers – Part 1: General Requirements
- EN/IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- EN/IEC 60601-1-4 Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: General Requirements for Programmable Electrical Medical Systems
- EN/IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability
- EN/IEC 62304 Medical Device Software – Software Life Cycle Processes
- EN/IEC 62366 Medical devices – Application of Usability Engineering to Medical Devices
- EN/ISO 21647 Medical Electrical Equipment — Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors

This declaration of conformity is valid from 01 June 2014.
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Authorised Signatory:

Paul Oris, Regulatory Affairs Representative

Date (Day Month Year)

02-06-2014