

Welch Allyn® DECLARATION OF CONFORMITY

SAP DIR No.: 80016542

Version: G

We declare, under our sole responsibility, that the product listed below conforms to the provisions of European Council Directive 93/42/EEC.

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| 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: | Flexiport EcoCuff |
| REF | ECO-09, ECO-10, ECO-11, ECO-12, ECO-MLT ECOCUFF-09, ECOCUFF-10, ECOCUFF-11, ECOCUFF-12, ECOCUFF-MLT |
| Annex: | VII |
| Classification: | I |
| Classification Rules: | I |
| GMDN Code and Term: | 34978 - Cuff, blood pressure, reusable |
| UMDNS Code and Term | 11072 - Bandlike devices encircling a body part or another device. Cuffs used in medical procedures or monitoring are typically filled with air or fluid. |
| Standards Applied: | ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process EN 1060-1 Non-Invasive Sphygmomanometers – Part 1: General Requirements EN1060-2 Non-Invasive Sphygmomanometers – Part 2: Supplementary Requirements for Mechanical Sphygmomanometers ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type |

Authorised Signatory:

Fiona Butler
Fiona Butler, Regulatory Affairs Representative

2013-04-19
Date