DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80018910 Version: B

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 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:	Welch Allyn SureTemp® Plus (690 & 692) Class I Accessories
REF	01802-110 Model 9600 Plus Calibration Tester 06137-000 SureTemp Calibration key 06138-000 SureTemp Plus Calibration Key
Medical Device Conformity Assessment Route Annex:	VII
Medical Device Classification:	I
Medical Device Classification Rules:	Annex IX, Rule 1 (for Calibration keys) Annex IX, Rule 12 (for Calibration tester)
GMDN Code and Term:	36871 Test instrument, thermometer
UMDNS Code and Term	15563 Devices designed to determine and/or adjust the accuracy of a measuring instrument so that the instrument can be used to make measurements that are accurate to within a specified tolerance. Most calibrators assess the medical instrument measurements deviations from a standard; others are high-accuracy simulators used to calibrate instruments that are capable of adjustment. A calibrator should be several times (e.g., 4 to 10 times) more accurate than the instrument being calibrated. Calibrators are also used in nuclear medicine to assess the radiation dose of radionuclides before their administration to patients.

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Standards Applied:	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN/IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (Note: applied to 01802-110)

Authorised Signatory:

Fiona Butler 2014-07-18 Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue