

## DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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), including amendment 2015/863.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153, USA
<b>EC REP</b>	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name <sup>1,3</sup> :	Welch Allyn SureTemp <sup>®</sup> Plus 690/692
<b>REF</b> <sup>1,3</sup>	901053 ELECTRONIC THERMOMETERS
<b>#</b> <sup>1,3</sup>	01690-200, 01690-201, 01690-300, 01690-300M, 01690-301, 01690-400, 01690-401, 01690-410, 01690-500, 01690-501, 01690-700, 01692-200, 01692-201, 01692-300, 01692-301, 01692-400, 01692-401, 01692-500, 01692-501, 01692-700, 01692-MC.
Radio equipment <sup>2</sup> :	n/a
Object of the declaration <sup>2</sup> :	n/a
Accessories and components <sup>2</sup> :	n/a
Medical Device Conformity Assessment Route Annex <sup>1</sup> :	II
Medical Device Classification <sup>1</sup> :	Ila,
Medical Device Classification Rules <sup>1</sup> :	Annex IX, Rules 5 & 10
GMDN Code and Term <sup>1</sup> :	14035 – Intermittent electronic patient thermometer, 37340 - Probe, thermometer, reusable, 13116 - Electronic thermometer probe cover


<sup>1</sup> applicable to the medical devices directive, 93/42/EEC


<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU

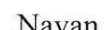
<sup>3</sup> applicable to the RoHS directive, 2011/65/EU

UMDNS Code and Term <sup>1</sup> :	14035 - Thermometers, Electronic, Thermistor/Thermocouple, Patient			
Notified Body <sup>1,2</sup> : (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2			
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):				
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances		
	EN IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance		
	EN IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests		
	EN IEC 60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems		
	EN IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability		
	EN ISO 80601-2-56	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement		
	EN IEC 62366	Medical devices – Application of usability engineering to medical devices		
	EN ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process		

Authorised Signatory:

  
Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

  
Date

  
Navan  
Place of Issue

<sup>1</sup> applicable to the medical devices directive, 93/42/EEC  
<sup>2</sup> applicable to the radio equipment directive, 2014/53/EU  
<sup>3</sup> applicable to the RoHS directive, 2011/65/EU