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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.

(110115), 1110	adding amendment 2015/805.		
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 ^{1,3} :	Welch Allyn SureTemp [®] Plus (690 & 692) Accessories Welch Allyn SureTemp [®] (678 / 679) Accessories (for use with SPOT VS)		
REF 1,3	901010, ACCESSORY, THERMOMETRY; 901113, ACCESSORY, THERMOMETRY		
#1,3	02892-000, 02892-100, 02893-000, 02893-100, 02895-000, 02895-100, 02678-000, 02678-100, 02679-000, 02679-100, 05031, 05031-ME, 05031-101, 05031-101-ME, 05031-105, 05031-110, 05031-125, 05031-150, 05031-750		
Radio equipment ² :	Not applicable, no radio		
Object of the declaration ² :	Not applicable, no radio		
Accessories and components ² :	Not applicable, no radio		
Medical Device Conformity Assessment Route Annex ¹ :	II		
Medical Device Classification ¹ :	IIa		
Medical Device Classification Rules ¹ :	Rule 5, Annex IX		

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

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

³ applicable to the RoHS directive, 2011/65/EU

Welch Allyn.

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GMDN Code and Term ¹ :	37340 – Probe, thermometer, reusable 13116 – Covers, Thermometer Probe		
UMDNS Code and Term ¹ :	13125 – Probes, Thermometer 13116 – Covers, Thermometer Probe		
Notified Body ^{1,2} : (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):	Number	Title	
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	
	IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	
	EN 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 60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems	
	EN 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability	
	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:

Jina Butlar Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative}

 $\frac{2018-03-06}{\text{Date}}$

Navan Place of Issue

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

² applicable to the radio equipment directive, 2014/53/EU ³ applicable to the RoHS directive, 2011/65/EU