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
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

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:

Fiona Butler — 2018-03-05 — Navan

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

Date

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