DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80017200 Version: G

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
REF	901053 ELECTRONIC THERMOMETER
#	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.
Medical Device Conformity Assessment Route Annex:	II
Medical Device Classification:	IIa
Medical Device Classification Rules:	Annex IX, Rules 5 & 10
GMDN Code and Term:	14035 – Intermittent electronic patient thermometer, 37340 - Probe, thermometer, reusable, 13116 - Electronic thermometer probe cover
UMDNS Code and Term	14035 - Thermometers, Electronic, Thermistor/Thermocouple, Patient
Notified Body: (CE 0297)	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main EC-certificate No. 314505 MR2

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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 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 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

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EN ISO 80601-2-56	Medical Electrical Equipment - Part 2-56: Particular requirements for basic safety and essential performances of clinical thermometers for body temperature measurement.

Authorised Signatory:

Fiona Butler — 2017-05-12 — Navan

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

Date

Place of Issue