DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: **80020006** 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 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity
- 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 Spot Vision Screener
REF	901029 Vision Screener
#	VS100
Medical Device Conformity Assessment Route Annex:	II
Medical Device Classification:	I(m)
Medical Device Classification Rules:	Class I according to Annex IX, Rule 12 with measurement function (m)
GMDN Code and Term:	46390 Visual Screening Analyser
UMDNS Code and Term	46390 Visual Screening Analyser
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 60601-1	Medical Electrical equipment – Part 1: General requirements for Safety.
	EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard Safety requirements for medical electrical systems.
	ISO 15004-2	Ophthalmic instruments-- Fundamental requirements and test methods: Part 2:Light hazard Protection

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2016-08-03
Date

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Place of Issue