DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016308 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 U.S.A.
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Audioscope 3
REF	901035 AUDIOMETER
#	23300, 23301, 92600, 92634, 92680, 92682, 92684, 92686, 92632F, 92632G, 92682F, 92682G, 92682S
Medical Device Conformity Assessment Route Annex:	II
Medical Device Classification:	IIa
Medical Device Classification Rules:	5 & 10
GMDN Code and Term:	61794 – Audiometer / otoscope
UMDNS Code and Term	10228, Audiometers
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
	ISO 10993-1	Biological Evaluation (entire 10993 Series, as applicable)
	IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	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
	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Authorised Signatory:

Fiona Butler 2017-04-21 Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue