

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.



Regulatory Affairs Representative
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland

Product Name: Audioscope 3



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: DQS Medizinprodukte GmbH,
(CE 0297) 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, Manager Regulatory Affairs
{EU Authorised Representative}

2017-04-21

Date

Navan

Place of Issue