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:

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 Classification: II
Medical Device Classification Rules: 5 & 10
GMDN Code and Term: 61794 – Audiometer / otoscope
UMDNS Code and Term: 10228, Audiometers
Notified Body: DQS Medizinprodukte GmbH,
August-Schanz-Str.21, 60433 Frankfurt am Main
EC-certificate No. 314505 MR2

Template DIR 80019151 Ver. C
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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}

Date: 2017-04-21  Place of Issue: Navan