



# DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80017196

Version: C

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.

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: Ear Wash System



29350, 29360, 293600, 29350CAN-D, 29350C-I, 29350DAN-I, 29350D-I, 29350E-I, 29350E-ID, 29350FCAN-D, 29350F-I, 29350G-I, 29350I-I, 29350P-I, 29350P-ID, 29350S-D, 29350S-I, 29350S-ID, 29350SW-I, 293600SCHP, 29352SCHP and 29360SCHP.

Annex: VII

Classification: I

Classification Rules: 5

GMDN Code and Term: 35025 - Syringe, irrigating, ear  
35348 - Speculum, ear

UMDNS Code and Term: 23526 - Irrigators, Ear Canal

Standards Applied: EN ISO 14971 Medical Devices - Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

Authorised Signatory:

Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

Date

Navan

Place of Issue