

SAP DIR No.: 80017302 Version: E

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, USA



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

Product Name: MicroTymp 3 Accessories



713290	Tip, Mt3, Large, Stepped
713983	Tip, Mt3, Medium, Stepped
713982	Tip, Mt3, Small, Stepped
713984	Tip, Mt3, Xlg, Stepped
713981	Tip, Mt3, X-Sm, Stepped
24625	Microtymp 3 Tips - 4 Extra Large (White)
24621	Microtymp 3 Tips - 4 Extra Small (Black)
24624	Microtymp 3 Tips - 4 Large (Green)
24623	Microtymp 3 Tips - 4 Medium (Blue)
24622	Microtymp 3 Tips - 4 Small (Gray)
24620	Microtymp 3 Tips - Case W/ 2 Ea Size Tip

Medical Device Conformity Assessment Route Annex: VII

Medical Device Classification: IIa

Medical Device Classification Rules: 5

**WelchAllyn®** DECLARATION OF CONFORMITY  
(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80017302 Version: E

GMDN Code and Term: 31940 - Ear phone cushion

UMDNS Code and Term: 11093 - Cushions

Notified Body: DQS Medizinprodukte GmbH,  
(CE 0297) August-Schanz-Str.21, 60433 Frankfurt am Main  
EC-certificate No. 314505 MR2

Standards Applied:	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN/ ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
	EN/IEC 60601-1-6	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
	EN 60645-5	Electroacoustics – Audiometric equipment – Part 5: Instruments for the measurement of aural acoustic impedance/admittance

Authorised Signatory:

  
\_\_\_\_\_  
Fiona Butler, Manager Regulatory Affairs  
{EU Authorised Representative}

2014-07-21  
Date

Navan  
Place of Issue