

# Declaration of Conformity

**Manufacturer:** Welch Allyn, Inc.

**Address:** 4341 State Street Road,  
Skaneateles Falls, NY 13153-0220  
USA

**Representative:** European Regulatory Manager,  
Welch Allyn Ltd.

**Address:** Navan Business Park,  
Dublin Road,  
Navan,  
County Meath,  
Republic of Ireland  
Tel. +353 46 9067700  
Fax. +353 46 9067756

Welch Allyn Inc declares under its sole responsibility that the Product:

**Name:**

- 22100 Set of Five for Pneumatic, Operating and Consulting Otoscopes - 2, 3, 4, 5 and 9mm.
- 22120 Set of Three SofSpec Specula 3,5, 7.0mm for Pneumatic, Operating and Consulting Otoscopes
- 21501 Insufflator Attachment for Pneumatic and Consulting Otoscopes
- 24420 SET OF 3 SOFSPEC SPECULA
- 71902 Rechargeable 3.5v Lithium Ion Handle complete with charging stand and Transformer EU
- 52133 KLEENSPEC OTOSCOPE SPEC. 3MM
- 52134 KLEENSPEC OTOSCOPE SPEC, 4
- 52135 5MM DISPOSABLE SPECULA
- 52432-U 2.75mm Universal KleenSpec Disposable Otoloscope Specula
- 52434-U 4.25 mm Universal KleenSpec Disposable Otoloscope Specula

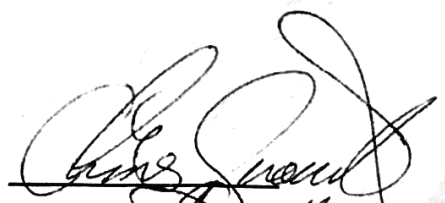
To which this declaration relates is in conformity with the following standards

EN 1441, EN 980, EN 1041.

The quality system that controls the manufacture of this product complies with the following standards, EN ISO 13485.

Following the provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Device is Class 1 under rule(s) 5 of Annex IX of this directive.

Quality / Regulatory Manager  
Welch Allyn Inc.

Signed: 

Date: 