

DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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, USA

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

Product Name^{1,3}: Stethoscope

REF_{1,3} 901039, STETHOSCOPE

#_{1,3} 17461, 17462P, 5079-122, 5079-122S, 5079-125, 5079-125P, 5079-125S, 5079-135, 5079-137, 5079-139, 5079-145, 5079-147, 5079-149, 5079-270, 5079-270S, 5079-271, 5079-271S, 5079-284, 5079-284S, 5079-285, 5079-287, 5079-289, 5079-291, 5079-321, 5079-321S, 5079-322, 5079-322S, 5079-323, 5079-323S, 5079-324, 5079-324S, 5079-325, 5079-325P, 5079-325S, 5079-326, 5079-326S, 5079-327, 5079-327S, 5079-327S-001, 5079-328, 5079-328S, 5079-UCOS, 59801, 59802, 59803, 59804

Radio equipment²: Not Applicable, No radio

Object of the declaration²: Not Applicable, No radio

Accessories and components²: Not Applicable, No radio

Medical Device Conformity Assessment Route Annex¹: VII

Medical Device Classification¹: I

Medical Device Classification Rules¹: I

¹ applicable to the medical devices directive, 93/42/EEC
² applicable to the radio equipment directive, 2014/53/EU
³ applicable to the RoHS directive, 2011/65/EU

GMDN Code and Term ¹ :	13755 - Stethoscope, mechanical	
UMDNS Code and Term ¹ :	13755 - Stethoscope, mechanical	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN/IEC 62366	Medical Devices – Application of Usability Engineering to Medical Devices

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2019-03-06

Date

Navan

Place of Issue

¹ applicable to the medical devices directive, 93/42/EEC

² applicable to the radio equipment directive, 2014/53/EU

³ applicable to the RoHS directive, 2011/65/EU