



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016475 Version: F

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: Stethoscope

REF 901039, STETHOSCOPE

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

Medical Device Conformity Assessment Route Annex: VII

Medical Device Classification: I

Medical Device Classification Rules: 1

GMDN Code and Term: 13755 - Stethoscope, mechanical

UMDNS Code and Term: 13755 - Stethoscope, mechanical

Standards Applied: EN/IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices



DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016475

Version: F

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2018-02-01

Date

Navan

Place of Issue