

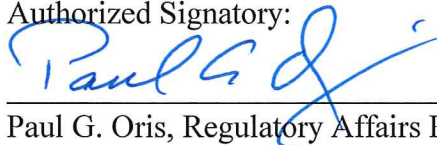
SAP DIR No.: 80016475

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 13153-0220	
EC REP	Regulatory Affairs Representative Welch Allyn, Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland	
Product Name:	Stethoscope	
REF	5079-321, 5079-321S, 5079-321M, 5079-322, 5079-322S, 5079-322M, 5079-323, 5079-323S, 5079-323M, 5079-324, 5079-324S, 5079-324M, 5079-325, 5079-325P, 5079-325S, 5079-325M, 5079-325PM, 5079-326, 5079-326S, 5079-326M, 5079-327, 5079-327S, 5079-327M, 5079-327M-001, 5079-328, 5079-328S, 5079-328M, 5079-28M, 5079-122, 5079-122S, 5079-122M, 5079-125, 5079-125P, 5079-125S, 5079-125SC, 5079-125M, 5079-125PM, 5079-270, 5079-270S, 5079-270SC, 5079-270M, 5079-271, 5079-271S, 5079-271SC, 5079-271M, 5079-284, 5079-284S, 5079-284SC, 5079-284M, 5079-135, 5079-135M, 5079-137, 5079-137M, 5079-289, 5079-139, 5079-139M, 5079-285, 5079-UCO, 5079-UCOS, 87-01-080, 5079-145, 5079-145M, 5079-147, 5079-147M, 5079-149, 5079-149M, 5079-287, 5079-287M, 5079-291M, 17461, 17462P	
Annex:	VII	
Classification:	I	
Classification Rules:	1	
GMDN Code and Term:	13755 - Stethoscope, mechanical	
UMDNS Code and Term	13755 - Stethoscope mechanical	
Standards Applied:	EN/IEC626366	Medical Devices – Application of Usability Engineering to Medical Devices
	EN ISO 14971:2007	Medical Devices – Application of Risk Assessment to Medical Devices

Authorized Signatory:


Paul G. Oris, Regulatory Affairs Representative

2013-11-06
Date