Welch Allyn® DECLARATION OF CONFORMITY

SAP DIR No.:	80016846	Version:	B

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 June1993 concerning medical devices.

Manufacturer's Name and Business Address:	Welch Allyn, Inc. 4341 State Street Road, Skaneateles Falls, NY 13153-0220 USA	
EC REP	Regulatory Affairs Representative Welch Allyn, Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland	
Product Name:	GS 900	
REF	44900, 44902, 44904, 44906, 44907, 44908, 44900-C, 44900-W	
Annex:	VII	
Classification:	I	
Classification Rules:	12	
GMDN Code and Term:	12276 - Light, examination	
UMDNS Code and Term	12276 - Lights designed to deliver intense focused lightning directly on the area where the examination is performed. These lights emit radiation in the visible spectrum; they are mostly used in dental and physician offices for patient examination and to perform other procedures (e.g., minor surgery). Examination lights are available in stand-alone (free standing), wall-mounted, ceiling-mounted, and table-top configurations	
Notified Body:	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main	
Standards Applied:	EN 60601	Medical Electrical Equipment- part 1: General requirements for basic safety and essential requirements
	EN 60601-1-1	Medical Electrical Equipment- part 1-1-General requirements for safety- Collateral Standard: Safety requirements for Medical Electrical Equipment
	EN 60601-1-2	Medical Electrical Equipment- part 1-2- General requirements for safety- Collateral Standard: Electromagnetic Compability- Requirements and Test

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	EN 60601-1-4	Medical Electrical Equipment- part 1-4- General requirements for safety- Collateral Standard: General requirements for programmable electrical medical systems
	EN 60601-1-6	Medical Electrical Equipment- part 1-6- General requirements for safety- Collateral Standard: Usability
	EN 62336	Medical devices -- Application of usability engineering to medical devices

Authorised Signatory:

Paul Oris, Regulatory Affairs Representative

2012-01-16
Date