DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016843 Version: E

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
- the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

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 Exam Light IV, GS 300, GS 600, GS 900
REF	901067 EXAM / PROCEDURE LIGHT 901014 ACCESSORY, LIGHTING
#	48810, 48812, 48814, 48816, 48817, 48818 44400, 44452, 44454, 44456, 44457, 44458, 44410, 44412, 44414, 44416, 44417, 44418 44600, 44602, 44604, 44606, 44607, 44608, 44610, 44612, 44614, 44616, 44617, 44618 44900, 44902, 44904, 44906, 44907, 44908, 44900-C, 44900-W 52630, 52640
Medical Device Conformity Assessment Route Annex:	VII
Medical Device Classification:	I
Medical Device Classification Rules:	12
GMDN Code and Term:	12276 - Light, examination

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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	
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 Compatibility - Requirements and Test
	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 62366	Medical devices -- Application of usability engineering to medical devices
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Authorised Signatory:

Fiona Butler — 2016-10-26 — Navan

Fiona Butler, Manager Regulatory Affairs {EU Authorised Representative} | Date | Place of Issue