



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



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



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

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|--------------------|--------------|--|
| 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, Manager Regulatory Affairs
{EU Authorised Representative}

2016-10-26

Date

Navan

Place of Issue