DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

SAP DIR No.: 80016467 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 U.S.A.
EC REP	Regulatory Affairs Representative Welch Allyn, Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name:	Illuminator and Trans Illuminator
REF	23857, 26030, 26035, 26530, 26535, 26538, 27000, 27050, 28100, 40510, 40515, 40520, 41100, 41101, 43300
Medical Device Conformity Assessment Route Annex:	VII
Medical Device Classification:	I
Medical Device Classification Rules:	1 & 12
GMDN Code and Term:	36761 Light Transilluminator 12276 Light Examination
UMDNS Code and Term	14130 Transilluminators

Standards Applied:	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	EN 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

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EN 60601-1-1	Medical Electrical Equipment – General Requirements for Safety – Collateral Standard: Safety requirements for Medical Electrical Systems

Authorised Signatory:

Fiona Butler — 2014-08-13 — Navan

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

Date

Place of Issue