DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

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, USA
EC REP	Regulatory Affairs Representative Welch Allyn Limited Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
Product Name[1,3]:	GS 777 Wall Transformer
REF [1,3]	901093, WALL TRANSFORMER
# [1,3]	77710, 77712, 77714, 77716, 77717, 77718
Radio equipment[2]:	Not Applicable, no radio.
Object of the declaration[2]:	Not Applicable, no radio.
Accessories and components[2]:	Not Applicable, no radio.
Medical Device Conformity Assessment Route Annex[1]:	VII
Medical Device Classification[1]:	I
Medical Device Classification Rules[1]:	12
GMDN Code and Term[1]:	36545 – Basic Power Supply

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU

UMDNS Code and Term[1]:	18557 - Any source of electric power, such as a power line or a battery. Batteries, direct-current electronic regulated power supplies, line power supply systems (including isolated and uninterruptible systems), and transformers are the main devices used in the field of medicine to deliver electric power to electric and electronic medical devices in hospitals and homes; batteries are also used as power supplies for implantable medical devices.	
Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):	Number	Title
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
	IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
	IEC 60601-1-2	Medical Electrical Equipment - Part 1- 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	IEC 60601-1-6	Medical Electrical Equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability

Authorised Signatory:

Fiona Butler

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2019-03-21
Date

Navan
Place of Issue

[1] applicable to the medical devices directive, 93/42/EEC
[2] applicable to the radio equipment directive, 2014/53/EU
[3] applicable to the RoHS directive, 2011/65/EU