

Welch Allyn[®] DECLARATION OF CONFORMITY

SAP DIR No.: 80017759

Version: A

We declare, under our sole responsibility, that the product listed below conforms to the provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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: GS 777 Wall Transformer

REF 77710, 77712, 77714, 77716, 77717, 77718

Annex: VII

Classification: Class I

Classification Rules: Rule 12

GMDN Code and Term: 36545 - Power supply, general-purpose

UMDNS Code and Term: 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:

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

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Authorised Signatory:

Fiona Butler
Fiona Butler, Regulatory Affairs Representative

2012-04-24
Date