

MANUFACTURER'S DECLARATION OF CONFORMITY*AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002***DECLARATION OF CONFORMITY PROCEDURES**

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Welch Allyn, Inc.

Business address: 4341 State Street Road
Skaneateles Falls, NY 13153 U.S.A.

Medical device(s): RetinaVue Network Software
REF: 901108 PACS Medical Image System

Classification: I

GMDN code and term: 36239 Picture archiving and communication systems

Scope of application: All

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

**Certificate number for
the product quality
assurance procedures:**

EC-certificate No. 314505 MP2012 (Unique ID 170660533)

Standards applied:

Standard	Version	Title
EN ISO 14971	2012	Medical devices - application of risk management to medical devices
IEC 62366-1	2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
IEC 62304	2006	Medical Device Software – Software Life Cycle Processes
NEMA PS 3.1 - 3.20	2016	Digital Imaging and Communications in Medicine (DICOM) Set
EN 1041	2008	Information Supplied by the Manufacturer of Medical Devices

Authorised signatory:



Joshua Kim
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2018.05.25
Date