



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## Welch Allyn, Inc.

4341 State Street Road  
Skaneateles Falls, NY 13153  
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Cardiopulmonary, Ears/Auditory, Endoscopic, Eyes/Vision, Vital Signs, Vital Signs Monitors, Data Management Systems, Episcopes and Sphygmomanometers as listed in the annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration No.	314505 MR2
Certificate unique ID	170584196
Effective date	2013-12-09
Expiry date	2018-12-08
Frankfurt am Main	2013-12-09

## DQS Medizinprodukte GmbH

Frank Graichen  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.





**Annex to Certificate**  
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Device family	Device	GMDN No.	Class
Cardiopulmonary	CP Series Electrocardiographs	11407	Ila
	CardioPerfect Workstation System	11407	Ila
	consisting of:		
	CardioPerfect Stress ECG	36145	Ila
	CardioPerfect Resting ECG	11407	Ila
	CardioPerfect Pro	11407	Ila
Ears/Auditory	MicroTymp Portable Tympanometric Instrument	41187	Ila
	AudioScope Screening Audiometer	41184	Ila
Eyes/Vision	SureSight Vision Screener	36387	Ila
Vital Signs	SureTemp and SureTemp Plus Clinical Electronic Thermometers	14032	Ila
		37340	Ila
	SureTemp Plus Probe Cover	43970	Ila
	Spot Vital Signs	57960	Ila
	Spot Vital Signs LXi	57960	Ila
	Connex ProBP Series Digital Blood Pressure Device	16173	Ila
	Ambulatory Blood Pressure Monitor (ABPM)	36888	Ila
	Mechanical Sphygmomanometer	16156	I(m)
Wall & Mobile Sphygmomanometer	16156	I(m)	
Vital Signs Monitors	Connex VSM Series Vital Signs Monitors	33586	Ilb
	Connex Integrated Wall System Series	33586	Ila
Data Management Systems	Connex VM Data Management Systems	44099	Ila
Skin/Physical Exam	Episcope	35484	I(m)
Monitoring Systems	Connex Central Station	38470	Ilb