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 and Monitoring Systems, Data Management Systems and Episcope 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	170660517
Effective date	2016-12-09
Expiry date	2021-12-08
Frankfurt am Main	2016-12-09

DQS Medizinprodukte GmbH

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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.

411.20 Version 1.0

Annex to certificate
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Device family	Device	GMDN No.	Class
Cardiopulmonary	CP Series Electrocardiographs	16231	IIa
	CardioPerfect Workstation System consisting of:	16231	IIa
	CardioPerfect Stress ECG	36145	IIa
	CardioPerfect Resting ECG	16231	IIa
	CardioPerfect Pro	16231	IIa
	Ambulatory Blood Pressure Monitor (ABPM)	36888	IIa
Ears / Auditory	MicroTymp Portable Tympanometric Instrument	36717	IIa
	AudioScope Screening Audiometer	61794	IIa
Eyes / Vision	SureSight Vision Screener	46390	IIa
	Spot Vision Screener	46390	I(m)
Single parameter Vital Signs	SureTemp Plus Clinical Electronic Thermometers	14035	IIa
	SureTemp Plus Probe Cover	13116	IIa
	Connex ProBP Series Digital Blood Pressure Device	45617	IIa
	Mechanical Sphygmomanometer	16156	I(m)
	Wall & Mobile Sphygmomanometer	16156	I(m)
Multi-parameter Vital Signs	Connex VSM Series Vital Signs Monitors	33586	IIb
Monitors	Connex Integrated Wall System Series	33586	IIa
	Propaq LT 802LTXX	36872	IIb
	Connex® Spot Monitor (CSM)	57960	IIa
	Spot Vital Signs	57960	IIa
	Spot Vital Signs LXi	57960	IIa
Monitoring Systems	Connex Central Station	38470	IIb
Data Management Systems	Connex VM Data Management Systems	57967	IIa
Skin/Physical Exam	Episcope	18021	I(m)

This annex is only valid in connection with the above-mentioned certificate.