



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, Endoscopic, Eyes/Vision, Vital Signs, Vital Signs Monitors and Monitoring Systems and Episcopes 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 | 170772722 |
| Effective date | 2020-11-20 |
| Expiry date | 2024-05-26 |
| Frankfurt am Main | 2020-11-20 |

DQS Medizinprodukte GmbH

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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 | 16231 | Ila |
| | CardioPerfect Workstation System | 16231 | Ila |
| | consisting of: CardioPerfect Resting ECG | 16231 | Ila |
| Eyes / Vision | Spot Vision Screener | 46390 | I(m) |
| | RetinaVue AutoDx-DR | 58713 | Ila |
| Single parameter Vital Signs | SureTemp Plus Clinical Electronic Thermometers | 14035 | Ila |
| | SureTemp Plus Probe Cover | 13116 | Ila |
| | Connex ProBP Series Digital Blood Pressure Device | 45617 | Ila |
| | Mechanical Sphygmomanometer | 16156 | I(m) |
| | Wall & Mobile Sphygmomanometer | 16156 | I(m) |
| | Braun Thermoscan® PRO 6000 Ear Thermometer | 17887 | Ila |
| | Braun Thermoscan® PRO 6000 Probe Cover | 13116 | Ila |
| Multi-parameter Vital Signs | Connex VSM Series Vital Signs Monitors | 33586 | Ilb |
| Monitors | Connex Integrated Wall System Series | 33586 | Ila |
| | Connex® Spot Monitor (CSM) | 57960 | Ila |
| | Spot Vital Signs 4400 | 57960 | Ila |
| Monitoring Systems | Connex Central Station | 59378 | Ilb |
| Skin/Physical Exam | Episcope | 18021 | I(m) |