

Welch Allyn  
 4341 State Street Road  
 P.O. Box 220  
 Skaneateles Falls, NY 13153-0220 USA  
 Telephone: 315.685.6663  
 Fax: 315.685.4091  
 www.welchallyn.com



## MANUFACTURER'S DECLARATION OF CONFORMITY

Made in accordance with Council Directive 93/42/EEC Annex II, Annex V, Annex VI or Annex VII, and relating to the devices listed below or in the attached Schedule.

<i>Reference:</i>	DOC-MDD-123, Revision 1
<i>Manufacturer's Name:</i>	Welch Allyn, Inc.
<i>Business Address:</i>	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153-0220
<b>EC REP</b>	Regulatory Affairs Manager – EMEA Welch Allyn, Ltd. Navan Business Park Dublin Road Navan, County Meath Republic of Ireland
<i>Medical Device(s):</i>	Welch Allyn CardioPerfect Workstation (Pocket PC ECG, PC-based Resting ECG, Exercise Stress ECG, Spirometry, ABPM, Holter): - See attached list for multiple products
<i>Classification:</i>	Annex II, Class IIa
<i>Classification Rules:</i>	Annex IX , Rule 10
<i>GMDN Code and Term:</i>	11407 <i>Electrocardiograph, general-purpose</i> 36145 <i>Stress exercise monitoring system, cardia:</i> 44422 <i>Electrocardiographic analyzer</i> 31683 <i>Adaptor, electrocardiograph, lead switching</i> 35562 <i>Cable/lead, electrocardiograph</i> 35035 <i>Electrode, electrocardiograph, single use</i> 41651 <i>Electrocardiographic Holter analyser software</i> 36888 <i>Patient data recorder, long-term, sphygmomanometer</i> 13680 <i>Spirometer, diagnostic</i>
<i>Scope of Application:</i>	All
<i>Registrar/Notified Body:</i>	Duetsche Gesellschaft zur Zertifizierung von Managementsystemen (DQS GmbH) Notified Body Number: 0297
<i>Quality Sys. Certificate:</i>	DQS GmbH certificate 343963 MR2 indicating conformance to DIN EN ISO 13485:2003.
<i>Standards Applied:</i>	IEC/EN 60601-1, IEC/EN 06061-1-1, IEC/EN 60601-1-2, IEC/EN 60601-1-4, IEC/EN 60601-2-25

*Authorised Signatory:*

  
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Huy Doan, Regulatory Affairs Manager

2008-06-20  
Date

## Cardioperfect Workstation Product List

### PC Based Resting ECG Systems

WA Part Number	Part Description
CPE-CN-EB	PRO Pocket ECG System Including Pat Cable
CPE-CN-EB-GB	PRO Pocket ECG System Including Pat Cable (UK)
CPRL-UN	PRO ECG Light System 600 Hz with USB Interface Excl. Pat Cable
CPR-UN	PRO ECG System with USB Interface Excl. Pat Cable
CPR-UN5	PRO ECG System with 5 Meter USB Interface Excluding Pat Cable
CPR-UN-EB	PRO ECG System with USB Interface Including Pat Cable
CPR-UI-EB	PRO ECG System with USB Interface and Adult Interpretation Incl. Pat Cable
CPR-UN-EB-D	PRO ECG System with USB Interface Including Pat Cable & Tab Electrode Set
CPR-UI-EB-D	PRO ECG System with USB Interface and Adult Interpretation Including Pat Cable & Tab Electrode Set
CPR-UN-UB	PRO ECG System with USB Interface Including Pat Cable
CPR-UI-UB	PRO ECG System with USB Interface and Adult Interpretation Including Pat Cable
CPR-SN	PRO ECG System with Serial Interface Excluding Pat Cable

### PC Based Resting ECG

[New material numbers available to support Thin Client ECG configurations](#)

102262	CPR100 Rest EG, IEC, Serial, non interp
102263	CPR100 Rest ECG, IEC, Serial, interp
102265	Charger, CardioPerfect PRO rec, UK pc
102266	Charger, CardioPerfect PRO rec, EU pc

### PC-Based Exercise ECG Test System Parts List

WA Part Number	Part Description
CPSL-UN	PRO Exercise ECG Light System with USB Interface Excluding Pat Cable
CPS-UN	PRO Exercise ECG System with USB Interface Excluding Pat Cable
CPS-UN5	PRO Exercise ECG System with 5 Meter USB Interface Excluding Pat Cable
CPS-UN-EC	PRO Exercise ECG System with USB Interface Including Pat Cable Clip (IEC)
CPS-UN-EP	PRO Exercise ECG System with USB Interface Including Pat Cable Push (IEC)
CPS-UN-UC	PRO Exercise ECG System with USB Interface Including Pat Cable Clip (AHA)
CPS-UN-UP	PRO Exercise ECG System with USB Interface Including Pat Cable Push (AHA)

## Document Change History

<i>Revision</i>	<i>Description</i>	<i>Date</i>
1	New Release using MDD format	11-02-2007