


# Auflistung Zertifizierungen

Burdick®  
HeartCentrix®  
Powerheart®  
Quinton®

Zulassungen und Zertifikate nach den Richtlinien der ERC und der AHA  
sowie den jeweiligen Landesgesetzen



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Certificate No. 2203-3-2007

**CERTIFICATE TO FOREIGN GOVERNMENT**

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address	
See Attached List (One Page)	<u>Manufacturer:</u> Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021	<u>Distributor:</u> Cardiac Science Corporation 500 Burdick Parkway Deerfield, WI 53531
	<u>Formerly known as:</u> Cardiac Science, Inc. 5474 Felt Road Minnetonka, MN 55343	<u>Formerly known as:</u> Cardiac Science, Inc. 5474 Felt Road Minnetonka, MN 55343

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

*Theresa McDonald*  
Theresa McDonald  
Chief, Regulatory Policy and Systems Branch  
Division of Risk Management Operations  
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY  
STATE OF MARYLAND

Subscribed and sworn to before me this 22 day of March month 2007 year.

*Donna H. Morgan*  
DONNA H. MORGAN  
NOTARY PUBLIC STATE OF MARYLAND  
County of Frederick  
My Commission Expires December 1, 2008



Page 1 of 1)

	NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS
Manufacturer:	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021
Formerly known as:	Cardiac Science, Inc. 5474 Felt Road Minnetonka, MN 55343
Distributor:	Cardiac Science Corporation 500 Burdick Parkway Deerfield, WI 53531
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## Foreign Country Certification Statement



May 19, 2008

**FOREIGN COUNTRY CERTIFICATION STATEMENT**

As a responsible official of Cardiac Science Corporation, I hereby certify that the company and products identified in the attached Certificate to Foreign Government continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A photocopy of the Certificate to Foreign Government may be used as long as this original statement is attached.

5/19/08  
Date

  
Cheryl Shell  
Vice President  
Regulatory and Clinical Affairs

STATE OF WASHINGTON )  
  )ss.  
COUNTY OF SNOHOMISH )

Subscribed and sworn to before me this 19 day of May, 2008.

  
Patricia D. Beauregard, Notary Public  
State of Washington, U.S.A.



Patricia D. Beauregard, Notary Public  
Address: 888 14001 14001  
Tel: 425-401-2000  
Tel: 425-401-2000  
CellPhone: 425-401-2000  
www.patricia-beauregard.com





# Auflistung Zertifizierungen

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## EC Zertifikat

**EC Certificate**

**Full Quality Assurance**

**No. CE 00357**

Issued to:  
**Cardiac Science Corporation**  
3303 Monte Villa Parkway  
Bothell  
Washington  
98021  
USA

In respect of:  
**The design and manufacture of electromedical devices (treadmills, electro-cardiographic diagnostic and monitoring systems, cardiac-stress test equipment, wireless medical telemetry systems, external defibrillators, electro-cardiographs, Holter systems, pulse oximeters, spirometers) and associated software**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.  
For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

  
Anne Boyd, Managing Director, BSI Product Services

First issued: 5 Dec 1994      Date: 21 Oct 2005  
Expiration Date: 4 Dec 2009

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**Conditions of Approval**  
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.  
This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

 BSI Product Services  
Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SD United Kingdom  
Tel +44 (0)1442 230442 www.bsi-global.com




# Auflistung Zertifizierungen

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## Powerheart® AED G3

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 CARDIAC SCIENCE

### Declaration of Conformity

**Manufacturer:** Cardiac Science Corporation  
3303 Monte Villa Parkway  
Bothell, WA 98021  
USA

**Quality Management Representative:** Ms. Cheryl Shea

**Authorized Representative:** MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany  
Tel.: +49 511 62 62 86 30  
Fax: +49 511 62 62 86 33

**Products:** Powerheart G3 (9300E) and its accessories

**Classification (MDD, Annex IX):** IIb, per Rule 9

I, the undersigned, hereby declare that the medical device, Powerheart G3 (Model 9300E) and its accessories, and bearing the CE Marking conform to the applicable provisions of EC Directive 93/42/EEC concerning medical devices.

This declaration is made on the basis of the Quality System Approval Certificate number: **FM 73165** issued by **BSI (ID# 0086)** in accordance with Annex II, Section 3 of this directive.

10/6/06  
Date

Cheryl Shea  
VP Regulatory Affairs & Quality Assurance

10/6/06  
Date

[Signature]  
President & CEO

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# Auflistung Zertifizierungen

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## Powerheart® AED G3 Automatic

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 **CARDIAC SCIENCE**

### Declaration of Conformity

**Manufacturer:** Cardiac Science Corporation  
3303 Monte Villa Parkway  
Bothell, WA 98021  
USA

**Quality Management Representative:** Ms. Cheryl Shea

**Authorized Representative:** MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany  
Tel.: +49 511 62 62 86 30  
Fax: +49 511 62 62 86 33

**Products:** Powerheart G3 Automatic (9300A) and its accessories

**Classification (MDD, Annex IX):** IIb, per Rule 9

I, the undersigned, hereby declare that the medical device, Powerheart G3 Automatic (Model 9300A) and its accessories, and bearing the CE Marking conform to the applicable provisions of EC Directive 93/42/EEC concerning medical devices.

This declaration is made on the basis of the Quality System Approval Certificate number: **FM 73165** issued by **BSI (ID# 0086)** in accordance with Annex II, Section 3 of this directive.

10/06/06  
Date

Cheryl Shea  
VP Regulatory Affairs & Quality Assurance

10/06/06  
Date

John A. Korman  
President & CEO

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# Auflistung Zertifizierungen

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## Powerheart® AED G3 PLUS

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**Declaration of Conformity**

**Manufacturer:** Cardiac Science Corporation  
3303 Monte Villa Parkway  
Bothell, WA 98021  
USA

**Quality Management Representative:** Ms. Cheryl Shea

**Authorized Representative:** MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany  
Tel.: +49 511 62 62 86 30  
Fax: +49 511 62 62 86 33

**Products:** Powerheart AED G3 Plus

**Classification (MDD, Annex IX):** IIb, per Rule 9

**Start of CE Marking:** 11/15/06

**GMDN Code:** 35972

I, the undersigned, hereby declare that the medical device, Powerheart AED G3 Plus, and bearing the CE Marking conform to the applicable provisions of EC Directive 93/42/EEC concerning medical devices.

This declaration is made on the basis of the EC Certificate number 00357, issued by **BSI (ID# 0086)** in accordance with Annex II, Section 3 of this directive.

Date 10/15/07 VP Regulatory Affairs & Quality Assurance  
*Cheryl Shea*

Date 10/15/07 President & CEO  
*John Henning*

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# Auflistung Zertifizierungen

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## Powerheart® AED G3 Automatic PLUS

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### Declaration of Conformity

**Manufacturer:** Cardiac Science Corporation  
3303 Monte Villa Parkway  
Bothell, WA 98021  
USA

**Quality Management Representative:** Ms. Cheryl Shea

**Authorized Representative:** MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany  
Tel.: +49 511 62 62 86 30  
Fax: +49 511 62 62 86 33

**Products:** Powerheart AED G3 Plus Automatic

**Classification (MDD, Annex IX):** IIb, per Rule 9

**Start of CE Marking:** 11/15/06

**GMDN Code:** 35972

I, the undersigned, hereby declare that the medical device, Powerheart AED G3 Plus Automatic, and bearing the CE Marking conform to the applicable provisions of EC Directive 93/42/EEC concerning medical devices.

This declaration is made on the basis of the EC Certificate number 00357, issued by BSI (ID# 0086) in accordance with Annex II, Section 3 of this directive.

10/15/07  
Date

*Cheryl Shea*  
VP Regulatory Affairs & Quality Assurance

10/15/07  
Date

*John M...*  
President & CEO

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# Auflistung Zertifizierungen

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## Powerheart® AED G3 Pro

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 CARDIAC SCIENCE

### Declaration of Conformity

**Manufacturer:** Cardiac Science Corporation  
3303 Monte Villa Parkway  
Bothell, WA 98021  
USA

**Quality Management Representative:** Ms. Cheryl Shea

**Authorized Representative:** MDSS GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany  
Tel.: +49 511 62 62 86 30  
Fax: +49 511 62 62 86 33

**Products:** Powerheart G3 Pro (9300P) and its accessories

**Classification (MDD, Annex IX):** IIb, per Rule 9

I, the undersigned, hereby declare that the medical device, Powerheart G3 Pro (Model 9300P) and its accessories, and bearing the CE Marking conform to the applicable provisions of EC Directive 93/42/EEC concerning medical devices.

This declaration is made on the basis of the Quality System Approval Certificate number: **FM 73165** issued by **BSI (ID# 0086)** in accordance with Annex II, Section 3 of this directive.

Date: 10/16/06

Cheryl Shea  
VP Regulatory Affairs & Quality Assurance

Date: 10/06/06

John P. Shea  
President & CEO

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