By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00357**

Issued To: **Cardiac Science Corporation**
N7 W22025 Johnson Drive
Waukesha
Wisconsin
53186-1856
USA

In respect of:

The design and manufacture of external defibrillators, accessories and associated software.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-05** Date: **2019-11-25** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00357

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NBOG Codes	Device Name	Intended Purpose
Class IIb		
MD 1103 MDS 7010	Powerheart AED G3 Elite Automatic	AED and accessories are used to diagnose and treat life threatening ventricular arrhythmias in patients who are unresponsive and not breathing. This is accomplished by monitoring the patient's ECG and delivering a defibrillation shock if necessary.
	Powerheart AED G3 Elite Semi-Automatic	
	Powerheart AED G3 Automatic	
	Powerheart AED G3 Semi-Automatic	
	Powerheart AED G3 Plus Automatic	
	Powerheart AED G3 Plus Semi-Automatic	
	Powerheart AED G3 Pro	
MD 1103	Powerheart G3 AED Defibrillation Pads	
	Powerheart G3 AED Pediatric Defibrillation Pads	
	Powerheart G3 Pro AED Defibrillation Pads (Polarized)	

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NBOG Codes	Device Name	Intended Purpose
MD 1103 MDS 7010	Powerheart G5 AED Automatic	AED and accessories are used to diagnose and treat life threatening ventricular arrhythmias in patients who are unresponsive and not breathing. This is accomplished by monitoring the patient's ECG and delivering a defibrillation shock if necessary.
	Powerheart G5 AED Semi-Automatic	
MD 1103	Powerheart G5 AED Defibrillation Pads	
	Powerheart G5 AED Pediatric Defibrillation Pads	
	Powerheart G5 AED CPR Feedback	

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Cardiac Science Corporation 500 Burdick Parkway Deerfield Wisconsin 53531 USA	**Design** **Manufacture**
Medical Device Safety Service (MDSS) Schiffgraben 41 D-30175 Hannover Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
5 December 1994		Initial Issue.
9 January 1995		Change of address from 2121 Terry Avenue, Seattle, WA, USA to 3303 Monte Villa Parkway, Bothell, WA, USA. Addition of electrodes, catheterisation analysis systems and pulmonary diagnostic systems to the scope of certification.
31 October 1996		Amendment to scope of certification. Replacement of "catheters" with "interventional medical devices (catheters, catheter accessories, hemostatic puncture closure devices)". Addition of Sherwood Davis and Geck in Norfolk Nebraska for sterilisation and in Deland, Florida for microbiological validation services, and Isomedix Inc., El Paso, Texas for sterilisation.
17 June 1998		Removal of the above devices and sub-contractors.
29 June 2000		Addition of Stairmaster Sports/Medical Products Inc. as sub-contract manufacturer of treadmills.
30 January 2002		Amendment to scope of certification. Add " and associated software". Addition of Mortara Instruments, Inc. in Milwaukee WI, USA for sub-contract manufacture of electrocardiographic diagnostic systems and the design of electrocardiographic monitoring systems. Renewal of certificate.

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15 October 2002		Removal of Stairmaster Sports/Medical Products Inc. as sub-contract manufacturer.
7 January 2004		Amendment to scope of certification. Addition of electro-cardiographs, holter systems, Pulse Oximeters, Spirometers. Addition of Quinton Cardiology, Inc. in Deerfield WI, USA as a second site for design and manufacture.
10 December 2004		Five years certificate renewal.
11 March 2005		Extension of scope to cover 'Automated external defibrillators'. Removal of 'catheterization analysis systems' from scope. Addition of sub-contractor 'Cardiac Sciences' for design and manufacture.
21 October 2005		Change of company name to 'Cardiac Science Corporation' Extension of scope to allow 'manual external defibrillators' Removal of sub-contractor 'Cardiac Sciences, Minnetonka' Addition of sub-contractor 'Cardiac Science Corporation, Lake Forest'.

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28 January 2011	7634251	The addition of Braemar Inc,1285 Corporate Centre Drive, Eagan Suite 150, Minnesota, 55121, USA, as a significant subcontractor for Manufacture.
12 December 2011	7766688	The addition of Criticare Systems (M) Sdn Bhd, Malaysia as significant subcontractor for Manufacture. The removal of activity Design from Cardiac Science Corporation, Deerfield, USA.
31 July 2012	7858251	Removal of 'Treadmills' and 'Holter Systems' and duplication of word 'electro-cardiographs' from the scope. Removal of 'Braemar Inc' as a significant subcontractor for manufacture.
8 November 2012	7900369	Change of address from 3303 Monte Villa Parkway, Bothell, WA, USA. to N7 W22025 Johnson Drive, Waukesha, Wisconsin, 53186-1856, USA.
8 December 2014	8216060	Renewal. Change of scope to 'The design and manufacture of external defibrillators, accessories and associated software'. Removal of 'Mortara instruments' as a significant subcontractor. Addition of'Celestica Electronics' as significant subcontractor for 'Manufacture'.

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Date	Reference Number	Action
20 March 2019	8859173	Traceable to NB 0086.
Current	9751078	Certificate renewal. Removal of subcontractors: • Criticare Systems, Manufacture • Celestica Electronics, Manufacture • Laguna Hills Cardiac Science Site, Design Added device table. Added activity of Design to subcontractor: Cardiac Science Corporation, Deerfield, USA. Removal of the GMDN code list.