

# Certificate

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## EC-Certificate

(Production quality assurance system)  
according to annex V of Medical Devices Directive 93/42/EEC

It is herewith confirmed by

### BSI Group Deutschland GmbH

Eastgate, Hanauer Landstrasse 115  
60314 Frankfurt am Main  
Germany

in its function as Notified Body (0535), that the manufacturer:

### Medical Computer Systems LTD.

Passage 4922, 4-2  
Zelenograd, Moscow, 124460  
Russia

concerning the

**active medical devices for diagnostic  
of non-vital physiological parameters**  
(products/variants specified in appendix)

fulfils the requirements according to Annex V of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the production and final inspection of the specified devices. For the placing on the market of class III products an Annex III certificate is required.

The appendix is part of this certificate and contains 1 page.

Report No.: SMO77149976

**Certificate No.: CE574163**



Notified by  
Zentralstelle der Länder  
für Sicherheitstechnik  
**ZLS-NB-67/12**

First Issue Date:  
13 November 2007.

Based on periodical surveillance  
this certificate is valid until  
12 November 2017.

Current Issue Date: 19 November 2012

  
Certification Body



## Appendix of EC-Certificate

(Production quality assurance system)

according to annex V of Medical Devices Directive 93/42/EEC

**Certificate No.: CE574163**

Medical devices of the manufacturer:

### Medical Computer Systems LTD.

Passage 4922, 4-2

Zelenograd, Moscow, 124460

Russia

Name of product	Variant	Item	UMDNS/ GMDN	Class
KARDIVAR system is a computer system for stress level evaluation by heart rate variability analysis			17-723	IIa
HeartVUE system is a system for non-invasive sceening of heart			17-898	IIa



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Zentralstelle der Länder  
für Sicherheitstechnik  
ZLS-NB-67/12

Frankfurt am Main, 19 November 2012

The logo for BSI Group Deutschland GmbH is a circular seal with the text 'BSI Group Deutschland GmbH' around the perimeter and 'Certification and Testing' at the top. In the center, the letters 'bsi.' are prominently displayed. Below the seal, there is a blue ink signature of 'Wilfried Balke' and the text 'Certification Body'.