



# 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**

**ZLS** 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

  
**bsi.**  
*Wilfried Galdobly*  
Certification Body

## Appendix of EC-Certificate

(Production quality assurance system)

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

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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	Ia
HeartVUE system is a system for non-invasive scening of heart			17-898	Ia



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

Frankfurt am Main, 19 November 2012

Certification and Testing · BSI Group  
bsi.  
Wilfried Bahlschlag  
Certification Body