

EC-Certificate

(Production quality assurance system)
according to annex V, section 3
Medical Devices Directive 93/42/EEC

It is herewith confirmed by the
Notified Body

**EUROCAT Institute for
Certification and Testing**
Quarat[®]Center, Wittichstraße 2
64295 Darmstadt, Germany
Identification No. 0535

that the manufacturer
„RC ART“ LLC
Akademika Postovskogo Str. 15
620146, Ekaterinburg, Russia

European representative
DENAS-Deutschland GmbH
Im Leuschnerpark 3
D-64347 Griesheim

concerning the medical device
nerve and muscle stimulator
(products/variants specified in enclosure)
fulfills the requirements according to Annex
V, section 3, Medical Devices Directive
93/42/EEC. The manufacturer has
established a quality assurance system for
the production and final inspection of
specified devices.

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

Based on the periodical surveillance the
certificate is valid until 02 March 2009.

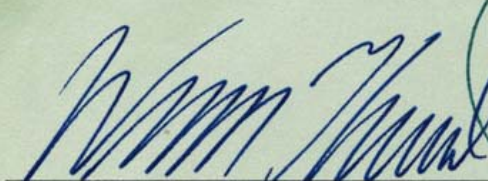
Certificate No.: CQ070361-V

CE 0535

Accreditation granted by
Zentralstelle der Länder
für Sicherheitstechnik

ZLS
ZLS-ZQ-236/04

Darmstadt, 05 February, 2007


Certification Body



Enclosure of EC-Certificate

(Production quality assurance system)

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

Certificate No.: CQ070361-V

Manufacturer

„RC ART“ LLC

Akademika Postovskogo Str. 15

620146, Ekaterinburg, Russia

European representative

DENAS-Deutschland GmbH

Im Leuschnerpark 3

D-64347 Griesheim

Medical devices concerned:

Name of product	Variant	Item spec.	UMDNS	class
Denas			16-255	Ila
Denas+			16-255	Ila
DiaDENS-T			16-255	Ila
DiaDENS-DT			16-255	Ila
DiaDENS-PC			16-255	Ila
DiaDENS-PCM			16-255	Ila
DiaDENS-Cardio			16-255	Ila

This annex replaces the annex of the Certificate No.: CQ070361 -V from 05 February 2007.

CE 0535

Accreditation granted by
Zentralstelle der Länder
für Sicherheitstechnik

ZLS

ZLS-ZQ-236/04

Darmstadt, 19 September 2007


Certification Body

