Certificate

EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) 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:

Zelenograd innovation-technology
center of medical equipment

JSC Zelenograd Innovation Technology Center of Medical Equipment - ZITC-MT
124498, Russian Federation, Moscow
Zelenograd, road 4806, 5/23

concerning the medical device

Defibrillator
UMDNS: 11-132
(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding section 4) Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.
For the placing on the market of class III products an additional Annex II section 4 certificate is required.

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

Report No.: SMO8307222
Certificate No.: CE 577269

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-248.10.04

First Issue Date:
August 30, 2012

With an annual surveillance
the regular certification cycle would be
May 12, 2016 until May 11, 2021.
Due to the closure of Notified Body NB0535
the certificate is valid until June 30, 2016.

Current Issue Date: May 12, 2016

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E. Schröder

Certification Body

Appendix of EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC
Certificate No.: CE 577269

Medical devices of the manufacturer:

Zelenograd innovation-technology center of medical equipment

JSC Zelenograd Innovation-Technology Center of Medical Equipment - ZITC-MT

124498, Russian Federation, Moscow
Zelenograd, road 4806, 5/23

Name of product	Variant	Item	UMDNS	Class
Defibrillator imPulse	PRO AND-P01 AND-P04 LCD AND-P05		11-132	IIb

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E. Schwab

Frankfurt am Main, May 12, 2016

Certification Body