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.: SMO7782679
Certificate No.: CE 577269

Current Issue Date: August 30, 2013

Certification Body

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

First Issue Date:
August 30, 2012.

Based on periodical surveillance
this certificate is valid until
June 14, 2016.

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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

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

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Frankfurt am Main, August 30, 2013

Certification Body