

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that



TRONITEK LLC.
15, Postovskogo str.
620146 Ekaterinburg
Russian Federation

for the scope

electro stimulators
(see attachment)

has introduced and applies a

Quality System

for the manufacture of the products concerned and carries out a final inspection as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2013-11-28
Valid until	2018-10-13
Registration no.	D1235500014
Report no.	E-D12355_2013-11-28
Stuttgart	2013-11-28

Head of Certification Body



Attachment of the certificate

No. D1235500014 date 2013-11-28

Product category	Product	Class	Product code
electro stimulators	Stimulator DiaDENS-PCM, Stimulator DiaDENS-Cardio, Stimulator DENAS-Vertebra	Ila	16-255



Head of Certification Body

