

# EC CERTIFICATE

Number: 2094050CE01

## Production Quality Assurance

**Directive 93/42/EEC on Medical devices, Annex V**  
(Devices in Class IIa, IIb or III)

Manufacturer:

**Elmedical Ltd.**

**29 Haharash St.  
Hod Hasharon 4501303  
Israel**

For the product category(ies)

**Hyperthermia treatment systems to the urinary bladder and urethra**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 2094050CN, initially dated 24 July 2006**  
**Addendum, initially dated 24 July 2006**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory. The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 August 2023  
Issued for the first time: 24 July 2006  
Reissued: 1 August 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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# ADDENDUM

Belonging to certificate: 2094050CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Hyperthermia treatment systems to the urinary bladder and urethra

Issued to:

**Elmedical Ltd.**  
**29 Haharash St.**  
**Hod Hasharon 4501303**  
**Israel**

This certificate covers the following product(s):

Pelvix TT system (class IIa)

The Pelvix TT system consists of:

- PelvixTT console (class IIa)
- UniThermia catheter set (Class IIa)
- DuoThermia catheter set (Class IIa)

Initial date: 24 July 2006

Revision date: 10 December 2012

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

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