EC CERTIFICATE

Number: 2110597CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

InSightec, Ltd.
5 Nachum Heth St.
PO Box 2059
Tirat Carmel 39120
Israel

For the product category(ies)

Focused Ultra Sound Therapy Devices for Tissue Ablation

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 2110597CN, initially dated 14 March 2008
Addendum, initially dated 27 January 2009

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 design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management 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 January 2023
Issued for the first time: 6 February 2006
Reissued: 1 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2110597CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Focused Ultra Sound Therapy Devices for Tissue Ablation

Issued to:

InSightec, Ltd.
5 Nachum Heth St.
PO Box 2059
Tirat Carmel 39120
Israel

This certificate covers the following product(s):

- ExAblate 2100 V1 (type 1.01 and 1.11) (Class IIb)
Indication for use: Ablation of soft tissue for treatment of benign tumors, including uterine fibroids and adenomyosis through focused heating of sections by means of ultrasound energy under MRI control

-ExAblate System 2100 V1 Bone application (type 1.01 and 1.11) and ExAblate System 2100 Bone CBS (type 2.0) (Class IIb):
Indication for use: Treatment of bone metastases, multiple myeloma, (local tumor control), bone denervation for local treatment of cancerous and benign primary and secondary bone tumors or facet joint syndrome.

-ExAblate System 4000 transcranial MR guided focused ultrasound system (Type 1) (Class IIb) intended for thermal ablation of targets in the thalamus, sub thalamus and pallidum regions of the brain.
Indication for Use: ExAblate 4000 transcranial MR guided focused ultrasound can be used for the treatment of neurological disorders (Essential Tremors, Tremor Dominant Idiopathic Parkinson's Disease – Unilateral) and Neuropathic Pain in the brain by heat induced focusing using ultrasound energy under full MR planning and thermal imaging control.

-ExAblate 2100 V1 (type 3.0) (Class IIb)
Indication for use: Treatment of locally-confined prostate cancer

Initial date: 27 January 2009
Revision date: 1 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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