

EC CERTIFICATE

Number: 2024682CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class I with measuring function)

Manufacturer:

MedicNRG Ltd.

Kibbutz Afikim 15148

Israel

For the product category(ies)

Electronic Apex Locators

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 2024682CN, initially dated 20 March 2003
Addendum, initially dated 20 March 2003

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, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

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 July 2019
Issued for the first time: 20 March 2003
Revised: 11 March 2016
Reissued: 1 July 2016

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2024682CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Electronic Apex Locators

Issued to:

MedicNRG Ltd.
Kibbutz Afikim 15148
Israel

This certificate covers the following product(s):

- ApexNRG-XFR
- ApexDAL
- ApexNRG-Blue
- ApexNRG-Rider

Initial date: 20 March 2003
Revision date: 21 July 2010

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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