

EC CERTIFICATE

Number: 2024682CE02

Production Quality Assurance

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

Manufacturer:

MedicNRG Ltd.
Kibbutz Afikim 15148
Israel

For the product category(ies)

Root canal preparation devices for the purpose of filling treatment

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 7 July 2014

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 July 2019
Issued for the first time: 7 July 2014
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

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ADDENDUM

Belonging to certificate: 2024682CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Root canal preparation devices for the purpose of filling treatment

Issued to:

MedicNRG Ltd.
Kibbutz Afikim 15148
Israel

This certificate covers the following product(s):

Gentlefile system

- Rechargeable hand piece
- Single use disposable head
- Stainless steel endodontic files

Initial date: 7 July 2014

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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