

EC CERTIFICATE

Number: 2002709CE01

Production Quality Assurance

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

(Devices in Class IIa, IIb or III)

Manufacturer:

Forum Engineering Technologies (96), Ltd

40 Hutsot HayotserSt.

Ashkelon 7878563

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:

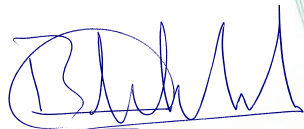
Certification Notice 2002709CN, initially dated 22 June 2000

Addendum, initially dated 22 June 2000

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 2023
Issued for the first time: 22 June 2000
Revised: 12 March 2020
Reissued: 1 July 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
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
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ADDENDUM

Belonging to certificate: 2002709CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Electronic Apex Locators

Issued to:

Forum Engineering Technologies (96), Ltd
40 Hutsot HayotserSt.
Ashkelon 7878563
Israel

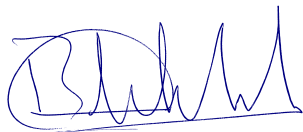
This certificate covers the following product(s):

- NovApex model N-31 (Class IIa)
- CanalPro Apex Locator Compact (Class IIa)
- BINGO PRO (Class IIa)
- Wirele-X (Class IIa)
- RomiApex™ A-15 (Class IIa)
- Endo-Eze Find (Class IIa)

Initial date: 22 June 2000

Revision date: 26 June 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
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