

# EC Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Formatk Systems Ltd.**  
**Yozma St. 3**  
**Tirat Hacarmel 3903203**  
**Israel**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**Effective date:** 2020-05-29

**Expiry date:** 2024-05-27

Report No.: 7304FS06F

Process No.: QS – 7304

Certificate No.: 7304GB410200529

Hamburg, 2020-05-29

MEDCERT Certification Body  
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Certificate of Conformity

Process No.: QS – 7304

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### List of products / product categories included in the scope of certificate

#### Medical devices for skin treatment by

- Intense Pulse Light (IPL)
- Nd:YAG Laser
- Diode Laser
- Radio Frequency (RF)

– End of list –

This appendix is integral part of the above-referenced certificate.  
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Formatk Systems Ltd.  
Yozma St. 3  
Tirat Hacarmel 3903203  
Israel

Hamburg, 2020.06.18

### Confirmation

We herewith confirm that the certification for

**Formatk Systems Ltd.  
Yozma St. 3 – Tirat Hacarmel 3903203 – Israel**

according to Directive 93/42/EEC, Annex II(3), with the certificate No.  
77304GB410200529,

covers the following devices:

Forma  
Forma Light  
Magma  
Magma Spark  
Magma Spark Pro  
Magma Spark Plus  
Alpha

Kind regards

Merkus Bianchi  
Director Certification