



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7304GB451230613

Final assessment report no.
7304AU10F

Effective date
2023-06-13

Expiry date
2026-04-13

This is to certify that the management system of
Formatk Systems Ltd.
3 Hayozma St., 3903203 Tirat Hacarmel, Israel
Facility ID: F006054
With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard
ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-06-13

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation


Markus Bianchi
Director Certification Body

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Activities and products/services covered by this certificate

Design and development, manufacture, and servicing of

- Medical devices for skin treatment with
 - Intense Pulse Light (IPL)
 - Nd:YAG Laser
 - Diode Laser
 - Radio Frequency (RF)

Sites covered by this certificate

Formatk Systems Ltd., 3 Hayozma St., 3903203 Tirat Hacarmel, Israel
Facility ID: F006054

Site-specific scope

Design and development, manufacture, and servicing of

- Medical devices for skin treatment with
 - Intense Pulse Light (IPL)
 - Nd:YAG Laser
 - Diode Laser
 - Radio Frequency (RF)