

EU Quality Management System Certificate

Certificate no.
7304GB448250221

Final Assessment Report no.
7304AU10F

Effective date
2025-02-21

Expiry date
2028-04-13

This is to certify that the quality system of

Formatk Systems Ltd.

3 Hayozma St., 3903203 Tirat Hacarmel, Israel

SRN: IL-MF-000022933

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded
in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2025-02-21



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Markus Biachi
Certification Body

The certificate is only valid when provided entirely with
all of its pages. To verify the validity of this certificate,
contact Medcert-Info@dnv.com



Certificate no.: 7304GB448250221
Place and date: Hamburg, 2025-02-21

Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

Sites covered by this certificate

Formatk Systems Ltd., 3 Hayozma St., 3903203 Tirat Hacarmel, Israel

Authorised representative

MedNet EC-REP IIb GmbH, Borkstrasse 10, 48163 Münster, Germany
SRN: DE-AR-000011192





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Products covered by this certificate

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0302	Z120402	General medicine therapeutic treatment instruments

Intended purpose

The Forma system intended purpose is to perform non-invasive skin treatments using IPL, RF, laser and mechanical rotation.

