EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Lumenis Ltd. Yokneam Industrial Park Hakidma Street 6, P.O.B. #240 Yokneam, 2069204 Israel

for the scope

Intense pulsed light (IPL), Radio Frequency (RF) and laser systems including delivery devices and associated accessories, tissue morcellators (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

 Valid from Valid until
 2021-02-09

 Valid until
 2024-05-26

 Registration no.
 D1368200005

 Report no.
 P19-00749-148069

Stuttgart 2021-01-08

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1368200005

Date 2021-01-08

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Product category	Class
Intense Pulsed Light (IPL) with accessories	IIb
Intense Pulsed Light (IPL), Nd:YAG, Erbium Laser with accessories	IIb
Diode Laser with accessories	IIb
Erbium Laser with accessories	IIb
CO2 Laser with accessories	IIb
Tissue Morcellators with accessories	IIb
Holmium Laser with accessories	IIb
Holmium, Nd:YAG with accessories	Ilb



Head of Certification Body

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