



CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/074-2017

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MIT hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. MIT certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

AMI INC.

MANUFACTURER

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Productive Site #2: 338-3, Majang-ri, Gwangtan-myeon, Paju-si, Gyeonggi-do, KOREA

DEVICE/S

Surgical Laser Devices

MODEL/S

- Diode Surgical Laser:
HACLRE, DI-REX, OCLA, SMILE-REX
- Q-Switched Nd:YAG Laser:
Q-MASTER, Q-MASTER PLUS, REX-Q
- Fractional CO2 Laser:
DERMAXEL, DX300, REX-CO, NEOXEL, NX400, BIOXEL, BX300, CO-LUX

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ORGANISMO NOTIFICATO - NOTIFIED BODY Nr. 0068