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C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/031-2017

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

MTIC Intercert 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. **MTIC Intercert 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.

MANUFACTURER:

CLASSYS Inc.

Registered office: Classys Tower 240, Teheran-ro, Gangnam-gu, Seoul, KOREA

Productive site: A-1501~1515, 15F, H Businesspark, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, KOREA

DEVICE/S:

Focused Ultrasound Therapeutic Equipment

**BRAND NAME/S
& MODEL/S:**

- ✓ Ulfit (UF1-M200)
- ✓ SCIZER (SC1-M400)
- ✓ ULTRAFORMER (UF2-M200)
- ✓ ULTRAFORMER III (UF3-M300)

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MTIC INTERCERT Certification Body

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