

#### Notified Body No. 1023 INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Zlin, Czech Republic - www.itczlin.cz

## **EC CERTIFICATE**

No. 12 0912 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products medical devices of Class IIa

### Diathermy treatment system operator console, high frequency

Model names: ESM-7600FREX

manufactured by company

### EunSungGlobal Corp.

#1316, 12 Cha, Daeryung Techno Town, 327-32, Gasan-Dong, Geumcheon-Gu, Seoul, Korea

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601822/2012, which is enclosed to this Certificate.

Conditions of this Certificate use and related information:

- It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
- The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 17th Sep 2017 at the latest.
- The Certificate validity is conditioned by positive results of surveillance audits.
- After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:

Issued in Zlín, on 18th September

RNDr. Radomir Čevelik resentative of the Notified Body No. 1023



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# **EC CERTIFICATE**

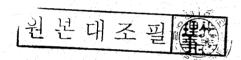
No. 12 0913 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIa

### Skin surface treatment system generator, multi-modality

Model names: ESM-9200IL

manufactured by company



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#1316, 12 Cha, Daeryung Techno Town, 327-32, Gasan-Dong, Geumcheon-Gu, Seoul, Korea

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- It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
- The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 17<sup>th</sup> Sep 2017 at the latest.
- The Certificate validity is conditioned by positive results of surveillance audits.
- 4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:

C E<sub>1023</sub>

Issued in Zlín, on 18th September

RNDr. Radomir Čevelik
Begresentative of the Notified Body No. 1023