



Islamic Republic of Iran  
Ministry of Health  
Medical Equipment Department

Certificate Number: **k/7/71860**  
Issued: **21/11/2010**  
Attached: **---**

## Certificate for Medical Device Production

In implementation of sections 11,12,13,17 article 1 of the Ministry of Health Mission Definition Law and note 5 related to article13 and note 2 related to article 14 the law related to Medical, Pharmaceutical and Foodstuff Affairs Regulations, as well as implementing of article 17 of medical equipment by-law and considering to the surveys done :

**The Production Unit : Farafan Engineering Co.**

**With ID No. : 1895**

**Factory Address : No.135, Molla Sadra St., Mirdamad Blvd., Alborz Ind. Zone, Ghazvin-Iran**

Is authorized to proceed with its production in accordance with the regulations of the respective ministry and the rules in force in the country.

Medical Device Specifications :

**Product's Name : Spacer -Respiratory Exerciser**

**UMDNS Code : 18084-11634**

**Specifications / Type : ----**

**Intended Use : ----**

**Device Category :**  Laboratory  Dentistry  Medical

**Specialized Group : General Use**

**Risk Class :**

Iran	A	B	C	D
Eu	I	II <sub>a</sub>	II <sub>b</sub>	III
	✓			

**Production Method :**

- 1-SKD  2- CKD  
 3-OBL  4- Under License  
 5-Independent

**Other instances : Extension of Certification No. k/7/78224 Dated 01/11/2009**

So the local use and the exportation of the above-mentioned device, regarding its intended use and observing the conditions mentioned in this permit , will be permitted.

*This certificate is valid up to*

**21/11/2011**

Director-general for medical equipment

**Saeed Reza Shahmoradi**



**Note:** This certificate after surveying the device described above , accompanied with related quality tests and also considering to its conformity with required regulations and announced standards is exclusively issued for aforementioned device and its addendum (if there is any) and It will be automatically null and void after the expiry date. Please note the overleaf remarks.

No 012080 J