Jordan Armed Forces – Arab Army

Directorate of pharmacy and medical supply

Evaluation Requirements for surgical instruments at Royal Medical Services Hospitals

1. **Letter from the local supplier contain the following information**

	Description of medical instrument	
	Name of local agent:	
	Contact name and phone number	
	Name of Manufacturer	
	Code number	
	Country of origin	
	Indication for use	
	evaluation sites/ specialization	
	period for evaluation for each site/ specialization	
	quantities offered for evaluation	

2. **<u>Certificate of origin</u> certified by the chamber of commerce in the export country issued by approved authority**
3. **Required certificates:**

   a) **For instruments of USA origin, a copy of a certificate of FDA approval <u>must be submitted with the request</u>**

   b) **For instruments of other origins, a copy of either a CE certificate (MDD)/TUV OR a certificate of FDA approval <u>must be submitted with the request</u>**

   c) **In all of the above cases certificates must be formally endorsed by JFDA.**

   d) **Bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the authorized agent/ distributor for the offered item.**

   e) **Any vendor not submitting all required certificates will be eliminated.**

4. **The vendor is responsible to ensure through official documents that classified medical instrument are manufactured in conformity with applicable quality system standards (ISO) and must provide the latest copy of the certificates of the following standards formally endorsed by the chamber of commerce of the manufacturing origin with the evaluation request :**

ISO 13485:2016	**Medical devices — Quality management systems — Requirements for regulatory purposes**
ISO 9001:2015	**Quality management systems — Requirements**
ISO 7153-1:2016	**Surgical instruments — Materials — Part 1: Metals**
ISO 7151:1988	**Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods**
ISO 7740:1985	**Instruments for surgery — Scalpels with detachable blades — Fitting dimensions**
ISO 7741:1986	**Instruments for surgery — Scissors and shears — General requirements and test methods**
ISO 13402:1995	**Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure**

5. **Catalogs and/or brochures that contain the code no. of the related medical instrument.**

6. **DRMS is not liable for any mishap/ damage that may occur during the evaluation process.**

7. **Specialized contact person should be available upon request by phone or by attending to the relevant site**

8. **Any request for evaluation will be accepted at the time where tender being offered without participating in the tender**

9. **The Royal Medical Services has the right to request any additional documents or requirements needed during the evaluation period.**

10. **The Evaluated surgical instruments shall be returned to the local agent, after they get final recommendation from Directorate of Pharmacy and medical supply.**

11. **The Royal Medical Services has the right to terminate the evaluation process without any prior notice if the item under evaluation cannot be utilized in the desired manner.**

12. **A fee of (100) JD should be paid for each application for evaluation after the approval of the committee to accept the evaluation.**