

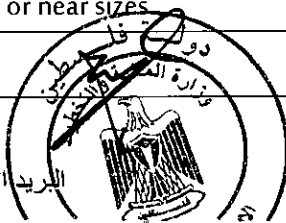


تنويه صادر عن مديرية اللوازم العامة بخصوص مناقصة رقم (2023/210)

شراء وتوريد جهازين orthopedic لصالح مستشفى رفيديا

بالاشارة للموضوع اعلاه، وبناء على الاستفسار الوارد إلينا بخصوص توضيح المواصفات الفنية الخاصة بالمناقصة المذكورة أعلاه يرجى العلم بإعتماد المواصفات الموضحة في الجدول أدناه:-

| Electric Orthopaedic Drill & Saw  | CHECK LIST | DEVIATIONS |
|---|------------|------------|
| Well-known manufacturer name with good reputation in Ministry of Health facilities, Manufactured in USA, EUR or Japan                   |            |            |
| All parts/components and accessories must be quoted separately and cleared in the financial offer                                       |            |            |
| Suitable to use for large and small bone surgery  |            |            |
| Electric/Battery operated with charger  |            |            |
| Including all attachments or Handpieces for Drill, Reamer, Oscillating saw, and Sagittal saw according to manufacturer recommendations. |            |            |
| <b>1- Rotary Dual handpiece:</b> For drilling and reaming with trigger adjustable speed, Forward and reverse operation.                 |            |            |
| <b>Complete with the following :</b>  |            |            |
| Jacobs chuck drill with key   |            |            |
| Quick coupling for drill bits   |            |            |
| Larg quick coupling   |            |            |
| Reduction drive unit  |            |            |
| Quick coupling for K-wires  |            |            |
| Drill hudson modified trinkle drill   |            |            |
| Jacobs reamer attachment  |            |            |
| Adjustable pin collect wire   |            |            |
| Drill bit different sizes (1.6 ,2, 2.8 ,3.2 ,4 , 4.8, 6.3 ) or near sizes   |            |            |
| Reamer quick locking device   |            |            |
| Different sizes of reamers to chose from (40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64 mm) or near sizes                          |            |            |





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| Krischner wire (round, double point & threaded 8 different sizes & shapes)  |  |  |
| <b>2- Sagittal saw handpiece with:</b>  |  |  |
| Large bone oscillating saw blades (2 different sizes)   |  |  |
| Large bone knee blades (2 different sizes)  |  |  |
| Large bone graft harvesting blades (2 different sizes)  |  |  |
| Large bone blades (2 different sizes)   |  |  |
| Micro sagittal saw blades (2 different sizes)   |  |  |
| <b>Complete with the following :</b>  |  |  |
| Sterilizing case with tray for Handpieces, Attachements & Batteries   |  |  |
| Battery Module for each handpiece   |  |  |
| Extra power module/battery Qty2   |  |  |
| Charger: charge four batteries at a time  |  |  |
| Cleaning brushes  |  |  |
| Special oil   |  |  |
| <b>OPTIONAL TO BE PRICED SEPARATELY ( Will be taken in consedration in technical &amp; financial analysis):-</b>                    |  |  |
| All Handpieces  |  |  |
| Detachable Power Cable  |  |  |
| Drill bit different sizes   |  |  |
| Sigital saw blades  |  |  |
| Reciprocating saw handpiece   |  |  |
| Reciprocating saw blades (different sizes & shapes)   |  |  |
| Sterilizing case  |  |  |
| Small fragment orthopedic set & Nancy Nails   |  |  |
|   |  |  |
| <b><u>DOCUMENTATION</u></b>   |  |  |
| Operating Manual (in original) soft and hard copies   |  |  |
| Service Manual (in original).soft and hard copies include Maintenance ,Troubleshooting, Electronic boards schematics , parts list . |  |  |
| <b><u>STANDERDS: Must be submitted with the offer ,with valid dates not less than 6 months</u></b>                                  |  |  |



## State Of Palestine

## Ministry Of Finance

## General Supplies Department

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| 1-For the Manufacturer & Equipment: Equipment should be FDA, European CE, UL or BIS approved product. certificate should be submitted.  |  |  |
| 2- Regulatory approval/certification: Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]). National local regulatory approval (of recipient country, as applicable) should be submitted |  |  |
| 3-Manufacturer should have ISO certification for quality standards .certificate should be submitted.Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices). General quality management (e.g. ISO 9001:2015). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices)   |  |  |
| <b><u>TRAINING</u></b>  |  |  |
| On-site training of 4 x operators to departmental faculty and staff for optimum usage till satisfaction.  |  |  |
| <b><u>INSPECTION</u></b>  |  |  |
| Inspection Authority: Biomedical Engineering Unit   |  |  |
| Shall inspect and test and where necessary reject the equipments after its arrival at the Hospital  |  |  |
| <b><u>Installation</u></b>  |  |  |
| Installation, Testing, Commissioning & Handing-over including site preperation if needed  |  |  |
| <b><u>Warranty</u></b>  |  |  |
| Warranty: 3 years, on site comprehensive warranty (labour & spares covering all parts of the units and items supplied), from the date of issue of installation certificate by Biomedical Engineering Unit   |  |  |
| 95% uptime guarantee should be given. In case downtime exceeds 5%, penalty in the form of extended warranty, double the number of days for which the equipment goes out of service will be applied.   |  |  |
| In case of agency removed from the agent or trasferred to other company, the old agent should be responsible of all warranty Implications, such as service , spare parts , etc  |  |  |





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|--|--|--|
| Should perform yearly calibration and preventive maintenance during warranty & if entered into AMC(includes unlimited breakdown calls) /CMC (which will include spare replacement, consumable spares,breakdown calls) .  |  |  |
| <b><u>MAINTENANCE &amp; REPAIR</u></b>   |  |  |
| The supplier must ensure the availability of expertise service and maintenance<br>The vendor should submit company profile including names and No. of engineers, training certifications preferably on the same product. |  |  |
| The system should be upgradable and all spare parts should be available for next 10 years after commissioning  |  |  |
| <b><u>TERMS AND CONDITIONS</u></b>   |  |  |
| The Supplied equipment should be complete with all accessories and consumables needed to work completely as specified  |  |  |
| Country of origin should be clear in the offer   |  |  |
| Country of source should be clear in the offer   |  |  |
| Date of manufacturing should be clear in the offer   |  |  |
| Original catalogue and detailed scientific literature of the quoted model to be enclosed.  |  |  |
| Number of units installed in Palestine if any (a list of the same model with serial number and location).  |  |  |
| The offer will not be taken in consideration in case of incomplete compliance sheet or any conflict between the catalogue/data sheet submitted and the compliance sheet  |  |  |
| The Vendor should submit Agency Agreement, or Sole distribution agreement or Authorization letter for sale and maintenance from Manufacturer, and it should have trained Engineer on this Machine)                       |  |  |
| Company must be registered in MOH  |  |  |

- يعتبر هذا التنويه جزء لا يتجزأ من وثائق المناقصة.

