Evaluation requirements for medical equipment at the Royal Medical Services

- ***Offers not complying with any of the special terms or the technical specifications shall be considered non-conforming with tender requirements.***
- ***Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.***

1. ***Required information:***
   - ***a) Contact name and phone number:***
   - ***b) Name of local agent:***
   - ***c) Name of Manufacturer:***
   - ***d) Model/ Catalogue number:***
   - ***e) Country of origin for the offered model:***
   - ***f) Country where the manufacturer is based:***
   - ***g) Date Launched (release date):***
   - ***h) Date of last upgrade/ update:***
   - ***i) Indication for use for the offered system:***
   - ***j) Brief description of the offered system:***
   - ***k) Suggested evaluation sites/ specialization:***
   - ***l) Suggested period for evaluation for each site/ specialization:***
   - ***m) Suggested patient population:***
   - ***n) Suggested quantities offered for evaluation:***
   - ***o) Installation base for the specific model offered for evaluation:***
   - ***p) Relevant published articles:***
2. ***Required certificates (must be submitted with the technical offer):***
   - **2.1** ***FDA approval & the relevant 510K clearance for equipment of USA origin (Country where the manufacturer is based).***
   - **2.2** ***CE certificate with the relevant CE number (Medical directive) for equipment of EU (European Union) origin (Country where the manufacturer is based).***
   - **2.3** ***UKCA certificate For Equipment of Great Britain origin (England, Scotland, Northern Ireland, and Wales) (Country where the manufacturer is based).***

2.4 ***ENTID (Enterprise Identification) with the relevant ARTG (Australian Register of Therapeutic Goods) number issued by the Therapeutic Goods Administration for Equipment of Australian origin (Country where the manufacturer is based).***

2.5 ***Establishment License with the relevant Device License issued by the Therapeutic Products Directorate for Equipment of Canadian origin (Country where the manufacturer is based).***

2.6 ***Japanese Pharmaceutical Affairs Law (JPAL) certification or approval for equipment of Japanese origin (Country where the manufacturer is based).***

2.7 ***Swissmedic (Swiss agency for therapeutic products) certification or approval for equipment of Swiss origin (Country where the manufacturer is based).***

2.8 ***Norwegian Medicines Agency certification or approval for equipment of Norwegian origin (Country where the manufacturer is based).***

2.9 ***The vendor is responsible to ensure through official documents that classified medical devices are manufactured in conformity with applicable quality system standards (ISO, IEC); (the international quality systems standard for medical device manufacturing ISO 13485) or ISO9001.***

2.10 ***Only for class I medical equipment, submission of a copy of Declaration of Conformity certificate for the offered model shall be accepted.***

2.11 ***With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent for the offered item.***

2.12 ***In all of the above cases (except 2.11) certificates must be formally endorsed by JFDA.***

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

3. Country of origin:

3.1. The country of origin of the main part (s) of the system must be one of the following:

USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France, Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia, Czech Republic, Luxembourg & Poland.

3.2. Accessories and consumables may be manufactured in other countries and/or by different manufacturers and should be approved by the manufacturer.

3.3. All offered items must be approved for sale in the same country of origin. An original and officially endorsed free-sale certificate from an authorised body must be included in the offer.

3.4. Except for X-ray based equipment, MRI, and nuclear medicine systems, equipment manufactured by reputable companies based in any of the countries mentioned in (3.1) will be taken into consideration regardless of the manufacturing site only:

a. If they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorised body must be included in the offer.

OR

b. If they are approved for sale in at least three of the countries mentioned in (3.1) (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).

4. Evaluation requests must include a priced list for accessories and consumables.

5. Where applicable, accessories and consumable items must be provide with each system on free of charge basis for the complete duration of the evaluation process/ the total number of patients/ cases or samples agreed upon evaluation.

6. Vendor must provide full technical and user specialist support for offered systems during the period of evaluation.

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

8. Where applicable, vendor is responsible for all pre-installation requirements that are necessary for the evaluation process.

9. Vendors must ensure the removal of evaluated systems from the evaluation sites at the end of the granted evaluation period.

10. 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.

11. For equipment that need consumables, consumables that are necessary for operating the system must be evaluated separately at medical consumables department.

12. A fee of (500) JD should be paid for each type of equipment provided for the evaluation after the approval of the committee to accept the evaluation.