To: All participants of Tender number ICB/PSA6/RDF/CT&MRI/MI/25/19

Ref.No. EPSA/06/840/04.

Date 24 MAR 2020

Subject: Clarification

Dear Sirs,

Reference is made to the above mentioned tender for CT scan and MRI machines. We hereby declare that the following clarifications should be considered in your offer.

1). Product Certification:-

Under section 3: Evaluation Methodology & Criteria, article 1.2 (a); For Item No. 1, 2 and 4 In addition to the requested certificates in the technical specification, valid EFDA Product Certificate, or up to date confirmation letter from EFDA for submission of dossier for registration and valid approved product certificates from SRA regions should be submitted along with the bid.

N.B: The following table shows list of regulatory schemes under Stringent Regulatory Authority (SRA) regions

S.No.	Stringent Regulatory Authority (SRA)	Acceptable Certificates/Evidences
1	European Union, United Kingdom, Switzerland	EC Full Quality Assurance Certificate
2	US Food and Drug Administration	Premarket Approval certificate
3	Health Canada	Medical Devices License and Summary report for class IV IVD
4	Therapeutic Goods Administration (TGA), Australia	TGA Full Quality Assurance Certificate
5	Japan Ministry of Health, Labour and Welfare (JMHLW)	JMHLW Minster's Approval Certificate

2). Lead Glass window for CT Scan – 16 slice should be 150cm * 100 cm with 2 mm thickness

3).The bidder should provide confirmation letter from the manufacturer along with its address (email, phone no., contact name, P.O.Box) ensures that CT Scan and MRI machines are fresh products (**N.B.** Refurbished products will not be accepted).

With Best Regards

Seifu Assefa Binagde
Pharmaceuticals and Medical Supplies Tender Management Directorate Director

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