CHECK LIST (List of documents to be completed and provided by Applicants)

ITB reference no: ITB/2020/16706
Name of applicant: [insert name of Applicant]
Date: [insert submission date]

Main tender

Documents mandatory:

1. Form A: Joint Venture Partner Information Form (if applicable)
2. Form B: Bid Submission Form
3. Annex 1_Form D_Technical Bid Form_ITB16706
4. Annex 2_Form C_Price Shedule Form_ITB16706
5. Form E: Performance Statement Form
6. Form F: No Adverse Action Confirmation Form
7. Form H: Commitment to Sustainability
8. Supplier sustainability questionnaire completed by Applicant
9. Copy of valid business license or Certification of incorporation of the Applicant
10. For JVs, copy of the business license of all parties constituting the consortium (if applicable)
11. Valid ISO 9001 certificate or equivalent quality management system certificate of Applicant
12. Copy of audited financial statements for the last 3 years
13. Gender statement
14. Valid ISO 14001 certificate or equivalent

For every Lot :

Documents mandatory:

1. Form G: Manufacturers Authorization Forms (where applicable)
2. Valid ISO 13485 certificate of manufacturers or equivalent quality management system certificate (where applicable)
3. Valid Regulatory certificates (CE, US FDA, UL…) and/or Declarations of conformity (where applicable)[1]
4. User, technical and maintenance manuals[2] (where applicable)
5. Local agent/s traceable references and proof of agreement / certification from manufacturers (where applicable)
6. Photos of offered products[3] (where applicable)

Documents optional:

1. List of countries where already supplied (current and past market)

For Lot 1: Lightweight Portable digital Xray system - Full kit

Documents mandatory:

1. List of accessories, consumables and spare parts (for every sub-item - where applicable)[4]
2. Sample chest X-ray images from individuals with different body thickness and input set up specified (in Kv, mAS, ms)
3. Screenshots of workstation / console with instruction

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[1] See details in *Section II Schedule of requirements_Section 3.4 a)*
[2] See details in *Section II Schedule of requirements_Section 3.4 b)*
[3] See details in *Section II Schedule of requirements_Section 3.4 e)*
[4] See details in *Section II Schedule of requirements_Section 3.4 d)*

4. List of CAD/AI software offered product is compatible with (specify CAD/AI software name and company name)

Documents optional:

1. Valid ISO 14971 certificate of manufacturers (where applicable)
2. Declaration from supplier that product was used for chest X-ray for TB screening/detection
3. Safety recommendations and limitation of use when used for chest X-ray for TB screening/detection
4. Recommended techniques and typical doses[5]

For Lot 2: Lightweight Portable digital Xray system - Basic kit

Documents mandatory:

1. List of accessories, consumables and spare parts (for every sub-item - where applicable)[6]
2. Sample chest X-ray images from individuals with different body thickness and input set up specified (in Kv, mAS, ms)
3. Screenshots of workstation / console with instruction
4. List of CAD/AI software offered product is compatible with (specify CAD/AI software name and company name)

Documents optional:

1. Valid ISO 14971 certificate of manufacturers (where applicable)
2. Declaration from supplier that product was used for chest X-ray for TB screening/detection
3. Safety recommendations and limitation of use when used for chest X-ray for TB screening/detection
4. Recommended techniques and typical doses[7]

Lot 3 - Computer-Aided Detection using Artificial Intelligence (CAD/AI) software

Documents mandatory:

1. Software verification and validation document/s
2. Installation and set-up procedure/s
3. Document/s demonstrating performance
4. Detailed description of required environment (hardware & software)
5. Screenshots of CAD/AI software interface and sample output (specify default cut-off threshold selections)
6. Link to demonstration website with login credential
7. List of portable X-ray systems offered product is compatible with (specify X-ray equipment name and company name)

Documents optional:

1. Valid ISO/IEC 27000 certificate of manufacturers
2. Valid ISO/IEC 14764 certificate of software maintainer
3. Declaration from supplier that product was used for TB detection from chest X-ray

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[5] See details in *Section II Schedule of requirements_Section 3.4 c)*
[6] See details in *Section II Schedule of requirements_Section 3.4 d)*
[7] See details in *Section II Schedule of requirements_Section 3.4 c)*