

Offline- Open Tender NATIONAL TENDER ENQUIRY DOCUMENT

**FOR SUPPLY, INSTALLATION, TESTING & COMMISSIONING
OF MEDICAL EQUIPMENTS**

For & on behalf of
FOR

**KALPANA CHAWLA GOVT. MEDICAL
COLLEGE, KARNAL**

Tender Enquiry Document No.:
HSCC/KCGMC/Medical Equipment/2016/off/02
Dated 01.09.2016

BY



HSCC (INDIA) LTD

(A GOVERNMENT OF INDIA ENTERPRISE)

Plot No. 6-A, Block-E, Sector-1, NOIDA (U.P.) - 201 301

PHONE: 0120-2540153

FAX: 0120-2542447

KALPANA CHAWLA GOVT. MEDICAL COLLEGE, KARNAL, HARYANA

GOVT OF HARYANA

Tender Enquiry No.: HSCC/KCGMC/Medical Equipment/2016/off/02 Dated 01.09.2016

NOTICE INVITING TENDERS (NIT) - Offline

HSCC (India) Ltd. for and on behalf of Director General, Medical Education & Research, Panchkula, Govt. of Haryana invites **offline bids** from eligible bidders, in single stage two bid system for Supply, Installation, Testing, Commissioning & Handing-over of various **Medical Equipments for Kalpana Chawla Govt. Medical College, Karnal, Haryana:**

Item No.	Name of the Article	Qty.	EMD (in INR)
1.	Dissection Table of stainless Steel 6'1"x2'x3'	15	15,000/-
2.	(a) Constant Temperature water bath (b) Incubator Electric with Thermostat	4 4	10,000/-
3.	Laboratory Refrigerator Electric	1	6,000/-
4.	Hot Air Oven	5	5500/-

Sl. No.	Description	Schedule
i.	On line sale of tender enquiry documents	01.09.2016 to 23.09.2016 upto 14:30 hrs
ii.	Place of sale of Tender Enquiry Documents	HSCC (India) Ltd, Plot No. 6-A, Block-E, Sector-1, Noida (U.P)-201301
iii.	Cost of the Tender Enquiry Document	INR 500/-
iv.	Pre Tender Meeting Date & Time	9.09.2016 , 11:00 hrs. IST
v.	Pre Tender Meeting Venue	Same as (ii) above
vi.	Closing date & time for receipt of Tender	23.09.2016 ., 15:00 hrs IST
vii.	Time and date of opening of Techno – Commercial tenders	23.09.2016 , 15:30 hrs IST
viii.	Venue of Opening of Techno Commercial Tender	Same as sr no. (ii) above

- TE Document fee Rs. **500/-** would be set in the form of account payee Demand Draft/Pay Order/Cashier's Cheque/Banker's Cheque drawn on a scheduled Bank in India/ cash in favour of "**HSCC (India) Ltd**" payable at New Delhi/ Noida.
- Bidder shall download the TE documents from the web site <http://eprocure.gov.in/cppp>, www.hsccltd.com, and submit its tender by utilizing the downloaded document, along with the required non-refundable fee as mentioned in Para 1 above.

3. All prospective bidders may attend the Pre Tender meeting. The venue, date and time indicated above.
4. Bidder shall ensure that their bid, complete in all respects, are dropped in the Tender Box located at **HSCC (India) Ltd, Plot No. 6-A, Block-E, Sector-1, NOIDA (U.P.) – 201 301** on or before the closing date and time, failing which the bid will be treated as late and rejected.
5. In the event of any of the above mentioned dates being declared as a holiday / closed day for the purchase organisation, the tenders will be sold/received/opened on the next working day at the appointed time.
6. The TE Document is not transferable.
7. **Bidder qualification Criteria:** Bidder should have turnover **Rs. 50 lakhs** per annum during last three financial years (i.e. 2013-14, 2014-15 & 2015-16)

7. Sealing of bid:

Envelop I: a. Bid Security (EMD)/ Registration certificate for the item quoted issued by NSIC/ DGS&D for exemption of EMD and bid document fee

b. Tender Document fee @ Rs. 500/-

Envelop II: a. Tender Form duly filled and signed

b. Turnover certificate during last three financial years (i.e. 2013-14, 2014-15 & 2015-16 certified by Chartered Accountant.

c. Technical compliance sheet with technical leaflets

Envelop III: Price Bid /Financial Bid

These above envelopes I, II & III shall be further sealed in one outer envelope super scribing name of item, item no. and TE document No.

9. Rejection of bid:

- If EMD & tender document fee / **Registration certificate for the item quoted issued by NSIC/ DGS&D for exemption of EMD and bid document fee**, as mentioned in the tender document not found in envelop-I, their bid will be rejected and Envelop –II & III will not open by the committee.

**CHIEF GENERAL MANAGER HSCC (I) Ltd.
For & on behalf of DGMR, Panchkula.**

Terms & conditions:-

1. **Period of Validity:** A bid shall remain valid for **120 days** from the date of opening of bid.
2. **EMD:** Tenderer shall furnish along with its tender, earnest money for amount as shown in the NIT. The earnest money shall be furnished in one of the following forms:

- i) Account Payee Demand Draft
- ii) Banker's cheque and
- iii) Bank Guarantee

The demand draft or banker's cheque shall be drawn on any commercial bank in India or country of the tenderer, in favour of the "HSCC (India) Ltd" payable at New Delhi/Noida. In case of bank guarantee, the same is to be provided from any commercial bank in India (as per the format in tender enquiry document). EMD to be valid for 165 days from the initial date of opening of the bid.

The tenderer who are currently registered and, also, will continue to remain registered during the tender validity period with Directorate General of Supplies & Disposals or with National Small Industries Corporation, New Delhi for the specific goods as per tender enquiry specification shall be eligible for exemption from EMD. Vague stipulations in the Registration Certificate such as "to customers' specification" etc. will not be acceptable for exemption from furnishing of earnest money. In case the tenderer falls in these categories, it should furnish copy of its valid registration details in its bid (with DGS&D or NSIC, as the case may be)

3. **Rate:** (a) The Prices should be quoted in Indian Rupees only. The rates quoted by the bidder shall be fixed for the duration of the contract and shall not be subject to adjustment on any account. All duties, taxes and other levies payable by the contractor under the contract shall be included in the quoted price. The rate quoted must be inclusive of Excise Duty, Packing & Forwarding charges, Sales Tax, Freight charges and Insurance charges.
(b) CMC price has to be quoted as per the format given in the bid.

4. **Sales Tax/ Vat:** Should be mentioned on price format.

5. **Evaluation:** The tenderers will be evaluated and compared separately for each item. The tenderer has to quote for the complete requirement given under the item. Comparison of the responsive tenders shall be carried out on all inclusive quoted price at Consignee site basis, inclusive of applicable taxes, duties, incidental services. The quoted CMC prices will also be added for comparison & ranking purpose for evaluation.

6. The bid submitted by MSME bidders shall be dealt as per the prevailing laws

7. **Name of Consignee:** The Director
Kalpana Chawla Govt. Medical College,
KARNAL (Haryana)

Name of the Purchaser : Director General, Medical Education & Research, Panchkula,
Govt. of Haryana

Name of the Consultant: HSCC(I) Ltd. Plot No. 6-A, Block-E, Sector-1, NOIDA (U.P.)

8. **Delivery Period: 30 days from date of Notification of Award/Purchaser order at consignee site.** The date of delivery will be the date of delivery at consignee site.
9. **Installation and commissioning:** Installation and commissioning shall be done **within 15 days** of receipt of the stores/ goods at site or within two weeks of handing over the site for installation, whichever is later.

- 10. Despatch Clearance:** No goods shall be despatched before issue of Despatch note issued by HSCC/KCGMC, failing which entire responsibility shall rest on the supplier.
11. **Warranty:** Warranty of equipments will be two years (on site) from date of commissioning & handing over to KCGMC/ Client.
12. **Performance Security:** Within fifteen (15) days from date of the issue of notification of award by the Purchaser/Consignee, the supplier, shall furnish performance security (as per the format in tender enquiry document) to the Purchaser/Consignee for an amount equal to ten percent (10%) of the total value of the contract, valid up to sixty (60) days after the date of completion of all contractual obligations by the supplier, including the warranty obligations, initially valid for a period of minimum 26 months (as applicable warranty period of 2 years) from the date of Notification of Award.
13. The Notification of Award/Purchaser order Constitutes the formation of legal binding contract between the parties, scope of supply will be governed by the technical specifications & other terms & conditions of the aforesaid Tender Enquiry document and its amendments /corrigendum (if any) issued.
14. The Time take on the part of HSCC / KCGMC / on account of despatch clearance will not be counted for delivery period /installation period.

15. Payment Terms:

- (i) 80% payment on submission of following document:-
- Copy of Purchase order.
 - Consignee receipt in original issued by KCGMC/HSCC.
 - Invoice in favour of consignee through HSCC for 80% claim
 - Warranty Certificate.
- (ii) 20% payment on submission of following documents:
- Copy of Purchase order.
 - Copy Consignee receipt issued by KCGMC/ Client.
 - Installation & commissioning or final acceptance certificate issued by KCGMC/HSCC.
 - Invoice in favour of consignee through HSCC for 20% claim.
16. Supply shall be accepted only after inspection and approval by the concerned authority at KCGMC.
17. **Liquidated Damage:** If the supplier fails to deliver any or all of the goods or fails to perform the services within the time frame(s) incorporated in the contract, the Purchaser/Consignee shall, without prejudice to other rights and remedies available to the Purchaser/Consignee under the contract, deduct from the contract price, as liquidated damages, a sum equivalent to 0.5% per week of delay or part thereof on delayed supply of goods and/or services until actual delivery or performance subject to a maximum of 10% of the contract price. Once the maximum is reached Purchaser/Consignee may consider termination of the contract.
18. **Insurance:** The supplier shall make arrangements for insuring the goods against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the following manner:

The supplier shall be responsible till the entire stores contracted for arrival in good condition at destination. The transit risk in this respect shall be covered by the Supplier by getting the stores duly insured for an amount equal to 110% of the value of the goods from ware house to ware house (consignee site) on all risk basis. The insurance cover shall be obtained by the Supplier and should be valid till 3 months after the receipt of goods by the Consignee.

19. Termination of Contract

19.1 The Purchaser/Consignee, without prejudice to any other contractual rights and remedies available to it (the Purchaser/Consignee), may, by written notice terminate the contract in whole or in part, if the supplier fails to deliver any or all of the goods or fails to perform any other contractual obligation(s) within the time period specified in the contract, or within any extension thereof granted by the Purchaser/Consignee

19.2 In the event of the Purchaser/Consignee terminating the contract in whole or in part, pursuant to sub-clause 19.1 above, the Purchaser/Consignee may procure goods and/or services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the supplier shall be liable to the Purchaser/Consignee for the extra expenditure, if any, incurred by the Purchaser/Consignee for arranging such procurement.

Unless otherwise instructed by the Purchaser/Consignee, the supplier shall continue to perform the contract to the extent not terminated.

20. Resolution of disputes

20.1 If dispute or difference of any kind shall arise between the Purchaser/Consignee and the supplier in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

20.2 If the parties fail to resolve their dispute or difference by such mutual consultation within twenty-one days of its occurrence, then, such dispute or difference shall be referred to the sole arbitrator appointed by **Director General Medical Education and Research, Govt. Of Haryana, Panchkula**. The award of the arbitrator shall be final and binding on the parties to the contract subject to the provision that the Arbitrator shall give reasoned award

20.3 Venue/seat of Arbitration: The venue of arbitration shall be at New Delhi, India.

21. Applicable Law and Jurisdiction

The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force. The contract shall be subject to the jurisdiction of Delhi court to the exclusion of all other courts.

22. Delivery/Delay in the supplier's performance

22.1 The supplier shall deliver of the goods and perform the services under the contract within the time schedule specified in the documents. The time for and the date of delivery of the goods stipulated in the schedule shall be deemed to be of the essence of the contract and the delivery must be completed not later than the date (s) as specified in the contract.

22.2 Any unexcused delay by the supplier in maintaining its contractual obligations towards delivery of goods and performance of services shall render the supplier liable to any or all of the following actions:

- (i) imposition of liquidated damages,
- (ii) forfeiture of its performance security and
- (iii) termination of the contract for default.

23 The bid submitted by the bidder should be accompanied with Power of Attorney in favour of signatory of TE documents.

24 Notwithstanding the above, the Purchaser reserves the right to accept or reject any quotations and to cancel the bidding process and reject all quotations at any time prior to the award of contract.

TENDER FORM

Date:

To,

Chief General Manager, HSCC
For & on Behalf of Director General Medical Education & Research (DGMER),
Govt. Of Haryana,
Panchkula

Ref. TE document no.

Item no:-

We, the undersigned have examined the above mentioned TE document, including all amendment/corrigendum issued the receipt of which is hereby confirmed. We now offer to supply and deliver, installation, commissioning _____ (*Description of goods and services*) in conformity with your above referred document terms for the sum of ___ (**NOT TO MENTION ANY PRICE DURING SUBMISSION IN TECHNICAL OFFER**) _____ (total tender amount in figures and words), as shown in the price schedule(s), attached herewith and made part of this tender.

If our tender is accepted, we undertake to supply the goods and perform the services as mentioned above, in accordance with the delivery schedule specified in the List of Requirements.

We further confirm that, if our tender is accepted, we shall provide you with a performance security of required amount in an acceptable form in terms of tender condition clause 12, for due performance of the contract.

We agree to keep our tender valid for acceptance as required in the tender clause condition 1, or for subsequently extended period, if any, agreed to by us. We also accordingly confirm to abide by this tender up to the aforesaid period and this tender may be accepted any time before the expiry of the aforesaid period. We further confirm that, until a formal contract is executed, this tender read with your written acceptance thereof within the aforesaid period shall constitute a binding contract between us.

We further understand that you are not bound to accept the lowest or any tender you may receive against your above-referred tender enquiry.

We confirm that we do not stand deregistered/banned/blacklisted by any Govt. Authorities.

We confirm that we fully agree to the terms and conditions specified in above mentioned TE document, including amendment/ corrigendum if any

We are fully agreed all the terms and conditions of TE document including amendment/ corrigendum /technical specification issued before opening of bid. In case, anywhere any conditional terms found in our bid, the same shall be treated as deleted/cancelled/ withdrawn from our bid. Whenever there is a conflict, the acceptance of all terms and conditions of TE document in the tender form shall prevail only.

(Signature with date)

(Name and designation) Duly authorised to sign tender for and on behalf of

Price Bid

Item no:

Name of item

Sr no.	Description of Goods	Make	Model no.	Qty.	Unit Price Rs.	Rate of VAT/Sales Tax e % added in Unit price	Total Amount Rs.
1.							

Amount in words: _____

Note: 1. Sales tax/VAT should be mentioned separately.

2. Unit price shall include all packing & forwarding, freight, insurance charges from ware house to consignee, local tax, duties, two year warranty, VAT/ taxes and other levies payable by the supplier under the contract.

Authorised Signatory
Name of the Company with Address

PRICE SCHEDULE FOR ANNUAL COMPREHENSIVE MAINTENANCE CONTRACT AFTER WARRANTY PERIOD

1	2	3	4					5
Item no.	BRIEF DESCRIPTION OF GOODS	QUANTITY. (Nos.)	Annual Comprehensive Maintenance Contract Cost for Each Unit year wise* (Inclusive of service tax) INR					Total Annual Comprehensive Maintenance Contract Cost for 5 Years [3 x (4a+4b+4c+4d+4e)] (Inclusive of service tax) INR
			1 st	2 nd	3 rd	4 th	5 th	
			a	b	c	d	e	

*** After completion of warranty period**

Authorised Signatory
Name of the Company with Address

BANK GUARANTEE FORM FOR EMD

To
HSCC I Ltd.
E-6A, Sector-1, Noida -201301

Whereas _____ (hereinafter called the "Tenderer") has submitted its quotation dated _____ for the supply of _____ (hereinafter called the "tender") against the purchaser's tender enquiry No. _____
Know all persons by these presents that we _____ of _____ (Hereinafter called the "Bank") having our registered office at _____ are bound unto _____ (hereinafter called the "Purchaser) in the sum of _____ for which payment will and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this _____ day of _____ 20____. The conditions of this obligation are:

(1) If the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.

(2) If the Tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity:-

- a) fails or refuses to furnish the performance security for the due performance of the contract.
- or
- b) fails or refuses to accept/execute the contract.
- or
- c) if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged

We undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition(s).

This guarantee will remain in force for a period of forty-five days after the period of tender validity and any demand in respect thereof should reach the Bank not later than the above date.

(Signature of the authorised officer of the Bank)

Name and designation of the officer

Seal, name & address of the Bank and address of the Branch



BANK GUARANTEE FORM FOR PERFORMANCE SECURITY/ CMC* SECURITY

To
Chief General Manager, HSCC I Ltd.
For & on Behalf of Director General Medical Education & Research (DGMER),
Govt. Of Haryana,
Panchkula

WHEREAS _____ (Name and address of the supplier) (Hereinafter called "the supplier") has undertaken, in pursuance of contract no. _____ dated _____ to supply (description of goods and services) (herein after called "the contract").

AND WHEREAS it has been stipulated by you in the said contract that the supplier shall furnish you with a bank guarantee by a scheduled commercial bank recognised by you for the sum specified therein as security for compliance with its obligations in accordance with the contract;

AND WHEREAS we have agreed to give the supplier such a bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the supplier, up to a total of. _____ (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the supplier to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the supplier before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the supplier shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid up to 26 months from the date of Notification of Award i.e. up to ----- (indicate date)

For CMC the BG shall be addressed to the Consignee

.....
(Signature with date of the authorised officer of the Bank)

.....
Name and designation of the officer

.....
Seal, name & address of the Bank and address of the Branch

Technical Specification of Equipment

Item No. 1

(a) Table Stainless Steel 6'1"x2'x3'

Is entirely made of S.S. (steel grade 1.4301), with a frame made of rugged torsion resistant S.S. profiles and 4 S.S. swivel locking castors (125mm dia.). The table top has a depth of approx. 15mm sloping towards the drain. Large radii on all inside corners provided for easy cleaning. A 10 L container with bayonet lock, mounted beneath the down spout, is applied to a rack in the base frame. An air tight compartment mounted beneath the table top serves for an odour free storage of drapes. It features a stainless steel full extension drawer and a removable S.S. tray provided with perforated plate and a removable lid.

Item No. 2

(a) Constant Temperature Water Bath (HIGH PRECISION) WITH STIRRER

Table top, double walled filled with high grade glass wool insulation between the two chambers. Outer chamber of is made of mildsteel with anti-rust and enamel coating which does not chip off easily and inner chamber is made of stainless steel and completely leakproof with ground welding to give smooth surfaces. Inner Chamber :- 430 (W) × 240 (H) × 265 (D) mm approx. Tightly controlled temperature with an accuracy of 0.1°C of digital temperature controller. Provided with a glass window for an easy inside view. Speed controlled stirrer is provided for continuous stirring of the medium to ensure uniform temperature throughout. Heating mechanism should have suitable heaters for fast and slow heating. Temperature is controlled from ambient to 100°C by electronic temperature controller with Indicator. Instrument should be ISI complaint and marked (or other equivalent standardization in case of imported equipment).

(b) Incubator Electric with Thermostat

Double walled construction. Inner chamber is made of highly polished Stainless Steel. Outer chamber is made of Steel Sheet, pretreated for surface treatment & finished with durable Powder Coated Paint. 75 mm gap between the walls and filled with glass wool. Inner chamber is fabricated with ribs to adjust shelves to any convenient height. Two doors. The outer door is insulated and is fitted with heavy hinges. Inner door is made of glass panel mounted in a wooden frame to facilitate inspection of samples, without disturbing the chamber temperature. Supplied with 3 removable shelves, made of perforated polished stainless steel sheet. Nichrome wire heating elements

properly insulated placed suitably for uniform temperature all over the space. Size of inner chamber: 605 (W) × 605 (H) × 605 (D) mm approx. Temp range: from 5°C above ambient to 60°C±0.5°C. Air circulating fan and Micro processor based PID temperature controller-cum-indicator, Ventilation: Air ventilator ports provided on both sides at top to ventilate, timer, Suitable to operate on 220 V single phase, 50 Hz, AC supply. Instrument should be ISI complaint and marked (or other equivalent standardization in case of imported equipment).

Item No. 3 Refrigerator

For storing blood plasma and other blood products, vaccines, other medical or pharmaceutical supplies. Also to cool samples or specimens for preservation. For faster pull-down and recovery times, it should have bypass refrigeration and microprocessor-based controls

Technical Specifications

1. Laboratory refrigerator should have 330 ltr capacities.
2. Temperature range from 2 deg C to 10 deg C.
3. It should have galvanized sheet steel construction, white powder coated and adjustable feet.
4. No welded joint to be exposed for rusting.
5. Insulation of high-grade pressure – foam material.
6. Lockable door with plastic magnetic sealing surround.
7. Automatic defrosting and condensed melt water evaporation.
8. Re-circulating air-cooling system.
9. Control panel with thermometer, main switch and temperature selection.
10. Hermetically enclosed, low noise, vibration proof compressor.
11. Visual and a caustic signal alarm system.
12. Epoxy coated outside finish and S/S interior.
13. Low noise, automatic defrosting, Freon free.
14. Should be CFC free.
15. Temperature indicators to be provided.
16. Power input to be 220-240VAC, 50Hz.
17. Should be CE or FDA or BIS approved product

Item No. 4 Hot Air Oven

1. Description of Function

1.1 Hot Air Oven is required for heating a sample under controlled conditions.

2. Operational Requirements

- 2.1 Microprocessor based system with PID-temperature controller with integrated auto diagnostic system with fault indicator.
- 2.2 Thermostatically controlled system.

3. Technical Specifications

- 3.1 External: Stainless Steel Casing: w x h x d: 850 x 600 x 700 mm (All dimensions will have a tolerance of 5 mm). Insulated stainless steel door with locking and rear zinc-plated steel.
- 3.2 Interior - w x h x d: 400mm x 450mm x 300 mm, 55 liters approx (all dimensions will have a tolerance of 5 mm) easy-to-clean interior, made of stainless steel, with supports on the three sides for three adjustable perforated stainless steel shelves.
- 3.3 Forced air circulation by quiet air turbine/Fan to ensure uniform temperature.
- 3.4 Fitted with load indicator and safety thermostat take over indicator lamp. LED indicator.
- 3.5 Temperature Variation +/- 1 deg C.
- 3.6 Temperature Range- ambient to 250 deg C.
- 3.7 Output available for data acquisition

4. System Configuration Accessories, spares and consumables

4.1 System as specified.

5. Environmental factors

- 5.1 The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%.
- 5.2 The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%

6. Power Supply

- 6.1 Power input to be 220-240VAC, 50Hz fitted with Indian plug.
- 6.2 Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications. (Input 160 – 260 V and output 220 – 240 V and 50 Hz).

7. Standards, Safety and Training

- 7.1 System should confirm to IS:6365-1971 (Reaffirmed 1995) with latest amendments in ISI specifications for Laboratory Electric Ovens. Alternatively, system should be FDA Approved or CE Certified.
- 7.2 Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450.
- 7.3 Should be compliant to ISO 13485: Quality systems - Medical devices - Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities.