

Amendments & Bidders Query

To,

Subject: Procurement of Medical Equipments for BJ Medical College, Ahmedabad.**Reference:** IFB No. HSCC/PMD/PMSSY-03/07-08/BJMC-9 dated: 30.04.2007

Dear Sirs,

Following replies to the pre-bid queries may please be noted:

Schedule 2: H₂O₂ Gas Plasma Sterilization System 50 Liters

Sr. No.	Original Specification	Amended Specification
1	<u>H₂O₂ Gas Plasma Sterilization System 50 Liters</u>	<u>H₂O₂ Gas Plasma Sterilization System 30 Liters</u>

Revised Specification for H₂O₂ Gas Plasma Sterilization System 30 Liters**Low temperature Plasma sterilization device 30 Liters**

Specifications:

USFDA APPROVED

System Specifications:

Unit Dimensions: H 840 mm D 840 mm, W 560mm

Unit Weight: 125 Kg

Chamber Dimension (H/D/W): 200/610/330mm, 30 Litres usable volume

Shelf Dimension : (2 shelves) 610 X 330 mm

Max. Weight per shelf: 11.3Kg

Electrical specifications:

Voltage/max.current: 99-132VAC, 47-63 Hz, 16 A: 180-264 VAC ,47-63 Hz,10A

Max Power Consumption 2000 W

Three Pin Plug 15 AMP

Documentation:

Printer: Print out of cycle data (Long and short Data)

Consumables:

- 1) Cassette: Prefilled H₂O₂ (Hydrogen Peroxide)WITH Leak Proof Indicator for user safety & handling
- 2) Indicator for Sterilisor
- 3) Biological Indicators with US FDA
- 4) Tyveck Wrappers for wrapping purpose Medical Grade

Sr. No.	Queries raised by the bidders.	Replies to bidders queries
1	<p>US FDA is provided by US department of Health & Human Service and its role is to monitor products for continued safety. <u>Asking for a US FDA approval for a product is making it a proprietary product.</u></p> <p>There are other international quality certification as well for the products such as TUV, CE, ISO, UKAS etc. We request you to kindly amend this specification point as CE certified or any international quality certification in order to make it universal.</p>	<p>Why is US FDA required when one already has ISO 9001/EN 46001CE/TUV/UKAS</p> <p>FDA 510 K certification is older and superior certification than CE (Refer to following excerpt from Medical Device Certification - CALISO Consulting.htm- The CE certification can be often achieved prior to the FDA's approval, thus enabling the device to be sold in Europe and generating substantial revenues. The requirements for CE certification are very strict but if the product is in advanced clinical investigation or IDE (Investigational Device Exemption) stages by the FDA, the CE certification can happen much quicker than the FDA's. At the same time the CE/ISO/TUV/UKAS Certification are mainly during validation of Manufacturing Process Where as the US FDA Validation is taking care of safety protocol from operational safety point of view. (We as an Indenting agent are more concern of operational safety validation than the manufacturing process validation)</p> <p>There are several instances in which FDA even alerts the user from using the unsafe devices either they are unsafe to use or do not meet the operational safety protocol, such surity is not covered under any if the other Validation as mentioned above.</p> <p>Here USFDA has been misunderstood as the agency allowing the party to sell in US but our objective to put the same is to ensure the safety protocol from operational Safety point,safety of the patient,safety of the paramedical staff, from enviornmental Safety point as well as the testing protocol.</p> <p>The accepted statistics at large is that most equipments with FDA certifications already have CE mark but the vice versa is not true.</p>

2	<p>Cartridge should be US FDA approved- this specification point also needs to be amended as CE certified or any international quality certification</p>	<p>Why do we need a US FDA certification on the cassette?</p> <p>As per medical devices certification act of FDA, all medical devices, which uses a toxic material, should be regulated. Hydrogen peroxide is a toxic gas and hence its concentration, packing and delivery mechanism should be FDA regulated.</p> <p>The sealed Hydrogen Peroxide cassette contains approximately 5.62 mLof hydrogen peroxide.The hazards are minimal due to the sealed cassette and quantity of the hydrogen peroxide</p>
3	<p>5 cycles per cassette: the minimum number of cycles per cassette should be mentioned and the vendors should also quote for cost of each cassette to be mentioned separately.</p>	<p>Why do we say 5 Cycles and why not “minimum 5 cycles”?</p> <p>Sterilization system works between defined parametric ranges. These ranges have been tested for boundary condition and certified by FDA. To enable the system to work under these defined parametric ranges, the input to the system has been standardized i.e., 5 cycles per cassette. Moreover, any good sterilization cycle should have a defined input as well as output, which make it all the more easier for control purposes.</p>
4	<p>Consumables biological indicators with US FDA -This specification point also needs to be amended as CE certified or any international quality certification</p>	<p>BIOLOGICAL INDICATOR – FDA why</p> <p>BI is the control system in a sterilizer, which validates whether sterilization is happening or not. It is in itself a medical device. Moreover, BI contains spores which requires safe manufacturing and delivery. Hence, a FDA certification ensures the quality standard.</p>

Schedule 3: H₂O₂ Gas Plasma Sterilization System 100 Liters

Revised Specification for H₂O₂ Gas Plasma Sterilization System 100 Liters

Specifications:

Low temperature Plasma sterilization device 100 Liters

USFDA APPROVED

System Specifications:

Unit Dimensions: H 166 Cm D 102 Cm W 76.5Cm

Usable Volume:100 Ltrs

Shelf Dimension Rectangular 2 Shelves 28 x 17 Inches Upper Shelves

30 x 13 Inches Lower Shelves

Max. Weight per shelf: 25Kg

Electrical specifications:

Voltage/max.current: Three Phase 20A/415 V

Socket for Three phase 5 lines

Max. Power consumption: 500W per Phase

Documentation:

Printer: Print out of cycle data (Long and short Data)

Cycle time and Load selection:72mts Long Cycle

& 55 mts Short Cycle

Room Conditions:

Temperature: 18-35 degree C

Humidity: 10 to 85 percents

Cassettes: Hydrogen Peroxide H2 O2

Cartridge : Sterilant H2 O2(Hydrogen Peroxide) in a cassette with leak proof indicator

CARTRIDGE SHOULD BE USFDA APPROVED

5 cycles per cassette

Microprocessor Control

Bi product should be Toxic Free

Sterile Product should Have Shelf Life 6 Months To 3 Years

Consumables:

1) Cassette: Prefilled H2O2 (Hydrogen Peroxide)WITH Leak Proof Indicator

2) Indicator for Sterilizer

3) Biological Indicators with US FDA

4) Tyveck Wrappers for wrapping Medical grade

Sr. No.	Queries raised by the bidders	Replies to bidders queries
1	<p>US FDA is provided by US department of Health & Human Service and its role is to monitor products for continued safety. <u>Asking for a US FDA approval for a product is making it a proprietary product.</u> There are other international quality certification as well for the products such as TUV, CE, ISO, UKAS etc. We request you to kindly amend this specification point as CE certified or any international quality certification in order to make it universal.</p>	<p>Why is US FDA required when one already has ISO 9001/EN 46001CE/TUV/UKAS</p> <p>FDA 510 K certification is older and superior certification than CE (Refer to following excerpt from Medical Device Certification - CALISO Consulting.htm- <i>The CE certification can be often achieved prior to the FDA's approval, thus enabling the device to be sold in Europe and generating substantial revenues. The requirements for CE certification are very strict but if the product is in advanced clinical investigation or IDE (Investigational Device Exemption) stages by the FDA, the CE certification can happen much quicker than the FDA's. At the same time the CE/ISO/TUV/UKAS Certification are mainly during validation of Manufacturing Process Where as the US FDA Validation is taking care of safety protocol from operational safety point of view. (We as an Indenting agent are more</i></p>

		<p>concern of operational safety validation than the manufacturing process validation)</p> <p>There are several instances in which FDA even alerts the user from using the unsafe devices either they are unsafe to use or do not meet the operational safety protocol, such surity is not covered under any if the other Validation as mentioned above.</p> <p>Here USFDA has been misunderstood as the agency allowing the party to sell in US but our objective to put the same is to ensure the safety protocol from operational Safety point,safety of the patient.safety of the paramedical staff, from enviornmental Safety point as well as the testing protocol.</p> <p>The accepted statistics at large is that most equipments with FDA certifications already have CE mark but the vice versa is not true.</p>
2	<p>Cartridge should be US FDA approved- this specification point also needs to be amended as CE certified or any international quality certification</p>	<p>Why do we need a US FDA certification on the cassette?</p> <p>As per medical devices certification act of FDA, all medical devices, which uses a toxic material, should be regulated. Hydrogen peroxide is a toxic gas and hence its concentration, packing and delivery mechanism should be FDA regulated.</p> <p>The sealed Hydrogen Peroxide cassette contains approximately 5.62 mLof hydrogen peroxide.The hazards are minimal due to the sealed cassette and quantity of the hydrogen peroxide</p>
3	<p>5 cycles per cassette: the minimum number of cycles per cassette should be mentioned and the vendors should also quote for cost of each cassette to be mentioned separately.</p>	<p>Why do we say 5 Cycles and why not “minimum 5 cycles”?</p> <p>Sterilization system works between defined parametric ranges. These ranges have been tested for boundary condition and certified by FDA. To enable the system to work under these defined parametric ranges, the input to the system has been standardized i.e., 5 cycles per cassette. Moreover, any good sterilization cycle should have a defined input as well</p>

		as output, which make it all the more easier for control purposes.
4	Consumables for plasma product – boosters are only required by one particular brand and there are other products available in the market that do not use boosters yet work efficiently and effectively. This specification point needs to be deleted/amended suitably.	<p>Booster why?</p> <p>It is clearly known that the greatest challenge in sterilization is to sterilize long narrow lumens(FROM 1 MT TO 2 MT). This system enables sterilization of long narrow lumens with the use of a booster. Moreover, the lumen claims of systems are also to be certified.</p> <p>The sealed Hydrogen Peroxide Booster contains approximately 0.18 mL of hydrogen peroxide .The hazards are minimal due to the sealed booster and quantity of the hydrogen peroxide</p>
5	Consumables biological indicators with US FDA -This specification point also needs to be amended as CE certified or any international quality certification	<p>BIOLOGICAL INDICATOR – FDA why</p> <p>BI is the control system in a sterilizer, which validates whether sterilization is happening or not. It is in itself a medical device. Moreover, BI contains spores which requires safe manufacturing and delivery. Hence, a FDA certification ensures the quality standard.</p>
6	Usable Volume	100 Litres.

All other terms & conditions of the bidding document remain unchanged.

Thanking You,

Yours faithfully,

(Pramod Somnathe)
Manager – Proc