Annex A

Technical Specifications for Ultrasonic Bath

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Technical Specifications for Ultrasonic Bath

1. Functional Requirements

1.1 The unit is intended to remove the biofilm on implants for diagnostic testing of implant associated infections.

2. General Requirements

2.1 The system shall be microprocessor-based in design.

2.2 The system shall be a table top model, compact design, lightweight with advanced ergonomics, robust in construction, simple to operate and easy to maintain.

2.3 The system shall support the use of containers to be suspended in the bath.

2.4 The system shall be capable of removing the biofilm without killing the bacteria, a quantitative assessment is possible.

2.5 The following items shall be available:

a. Implant containers

b. Suspension moulds to hold the containers in the bath

c. Containers size to fit is at 135x102x282 mm.

2.6 The system shall be an Ultra-sonic machine with ultrasonic bath.

2.7 The system shall be frequency at 38 to 40 kHz. Noise emitted should be minimal; It should not exceed an equivalent sound pressure level of 85 decibels over an 8 hour workday.

2.8 The unit shall be automated that required minimum user interaction and handling.

2.9 Provision of scientific evidence / references / medical literature that the system supplied can be used for diagnostic testing for implants associated infections.

2.10 The system shall maintain the accuracy and there shall be no necessity to calibrate the unit before every use.

3. Electrical Requirements

3.1 The system shall be capable of operating directly from a 230V ± 10%, 50 ± 2 Hertz, single-phase AC supply and equipped with 13A moulded construction power plug (BS1363/A type).

3.2 All accessories shall be fully integrated, with a single power plug.

3.3 The system shall be protected from transient power disruptions during use. The disruption shall not affect the performance of the unit.

3.4 The unit shall be equipped with self-tripping circuit breaker for protection against overload.

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4. Safety Requirements

4.1 The construction of the unit shall ensure a sufficient degree against safety hazards caused by overflow, spillage, leakage, humidity and ingress of liquids, cleaning, sterilisation and disinfections.

4.2 The enclosure shall be secure and provide adequate protection against moving and electrically energised parts.

4.3 Switches and controls should be protected against penetration of fluids.

4.4 Switches and controls shall be protected against accidental setting changes.

4.5 The controls (i.e. switches, knobs, etc.) should be visible and clearly identified, and their function should be self-evident. Device design should prevent misinterpretation of displays and controls settings.

4.6 The unit should resist tipping over during use and transport.

5. Standards

5.1 The system shall fully conform to the following:

a. IEC 61010-1, safety requirements for electrical equipment for measurements, control, and Laboratory use;

b. IEC 61326-1, Standard for Electromagnetic Compatibility;

c. IEC 61000-4-x general requirements for safety and electromagnetic compatibility requirements and tests

d. IEC 60529 (1989), Degrees of protection provided by enclosures (IP code).

e. Internationally available standard in the particular requirements for safety and performance for Bacterial Culture System;

f. Shall have FDA clearance

5.2 The system shall fully comply with the latest Republic of Singapore Health Product Act and Regulation for medical devices. The system which classified as Low-moderate Risk (Class C), Moderate-high Risk (Class B) and High Risk (Class A) and which delivery on or after 1st May 2010 to hospital shall be registered to Singapore Medical Device Register (SMDR) of Health Sciences Authority (HSA). The tenderer must submit the certificates of registration for Good Distribution Practice For Medical Devices(GDPMDS) from HSA .

6. Technical Requirements

6.1 The Contractor shall furnish full technical specifications of the tendered Article together with the tender submission.

7. Standard Accessories

7.1 All standard accessories and consumables shall be **listed with itemised prices and be included in the system base price.**

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7.2 All necessary containers for intended applications as well as other accessories, cables and connectors necessary for the smooth and safe operation of the system shall be quoted and included in the base price.

8. Optional Accessories

8.1 All optional accessories shall be listed with itemised prices.

9. Installation / Commissioning Requirements

9.1 The Contractor shall inspect the site and fully acquaint himself with the nature of the work and the local conditions and facilities available, including water, drainage, ventilation and air-conditioning, where the Article is to be installed, before submitting his tender. He should also utilise other means he may prefer or consider necessary in order to fully ascertain other matters, site accessibility to equipment, conditions or constructions that may have a bearing on, or in any way affect the preparation of his tender. No claim for extra payment will be entertained by the Hospital owing to the Contractor's neglect in this regard and any unforeseen difficulties for which provision is not made. This will in no way relieve the Contractor from the full execution of all works necessary to complete the installation. A Contractor, by the fact of submission of a tender, shall be deemed to have accepted all conditions and stipulations of this clause, which shall be binding on the Contractor.

9.2. For the testing and commissioning, the contractor shall be represented by competent staff, suitably equipped with all necessary calibrated test and measuring instruments including electrical safety analyser with printout, who shall test and commission the Articles in the presence of and to the satisfaction of the Company's authorised representatives. **(Please refer SCC.3, Clause 11 for details)**

9.3 All mains operated electrical Articles shall be complete with suitably insulated and sheathed three-core hospital grade flexible power cords of voltage and current rating appropriate to the Articles. Article for operating theatre shall be supplied with flexible power cords each of not less than 5m length, although the exact length shall be negotiable later. The flexible power cord shall be fitted with three-pin, high impact, unbreakable nylon body electrical plug meeting BS 1363/A or equivalent. The plug shall be of good quality consistent with hospital safety, moulded construction type and shall be equivalent to "Volex V.1307W", BICC 3583-07", or MK Toughplug", 13A nylon unbreakable plugs. The plug shall be wired in conformance with sub-clause 6.5 of IEC 60601-1.

10. Additional Requirements

10.1 The supplied equipment and accessories must be of hospital-grade and shall comply with national and internationally recognised Standards and applicable Standard Systems.

10.2 The Contractor shall provide *test certificates* from an internationally recognised testing body attesting to compliance with recognised standards. **** If certificates for the STATED compliance are not provided during the submission, it shall be considered as non-compliant to the standard.***

10.3 The Contractor is expected to successfully commission the Article 14 days from the date of delivery. Failure of which the Company has the right to return the Article to the Contractor. No claim for payment will be entertained by the Company. A Contractor, by the fact of submission of a ender shall be deemed to have accepted all conditions and stipulations of this clause, which shall be binding on the Contractor.

10.4 The testing and commissioning of the Article shall be in accordance with clause 11 of ***SCC.3** called under Material Management Department. No payment shall be made if any of the stated requirements under this clause were not met. Notwithstanding the incomplete

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acceptance of the Article, the Company has the right to utilise the Article while waiting for any incomplete supply to be delivered.

10.5 The Contractor should be a direct representative/distributor of the manufacturer for all Articles including accessories.

10.6 The Contractors shall submit a letter of appointment from the manufacturer as sole agent in Singapore for the articles offered. The Contractor shall also specify:

a) The number of years that they have been appointed agent; and

b) The expiry date of the current agency agreement;

c) The expected date of discontinuation of this product.

10.7 All mains operated electrical Articles shall be complete with suitably insulated and sheathed three-core hospital grade flexible power cords of voltage and current rating appropriate to the Articles. Article for operating theatre shall be supplied with flexible power cords each of not less than 5m length, although the exact length shall be negotiable later. The flexible power cord shall be fitted with three-pin, high impact, unbreakable nylon body electrical plug meeting BS 1363/A. The plug shall be of good quality consistent with hospital safety and shall be equivalent to “Volex V.1307W”, BICC 3583-07”, or MK Toughplug”, 13A nylon unbreakable plugs. The plug shall be wired in conformance with sub-clause 6.5 of IEC 60601-1.

10.8 The warranty shall cover unlimited breakdown service calls, calibration and software upgrades, at no additional cost. The *preventive maintenance* of the unit shall be in accordance with the manufacturer's procedure and interval. The regular preventive maintenance shall include testing in compliance to IEC 60601.1. *The Contractor shall at the time of submission, provide a copy of the preventive maintenance checklist, method and procedures.* The Contractor shall provide *back-up units* during the warranty period while the unit is undergoing corrective repair by the Contractor.

10.9 In the event of equipment breakdown and the downtime exceeds 24 hours, the Contractor shall be responsible for arranging a loan unit of similar capacity to be used by the Company. All cost shall be borne by the Contractor.

10.10 The successful Contractor shall provide appropriate In-service training for Physicians, Nurses, Clinical staff, Laboratory Technologist, etc and Technical Service Training for Biomedical Engineers/Technicians. A qualified full time trainer shall conduct the training. In-service training shall be provided by qualified clinical instructors who are not sales personnel. Technical service training shall be provided by a qualified engineer. The technical service training shall be *comprehensive* and provided to a level such that the Company's nominated service personnel are able to:

a. Apply or handle; and
b. Install, repair, calibrate, maintain or overhaul

all models of equipment purchased from the Contractor. The outline of the Technical service training programme must include - installation instructions; system overview with block diagram; detailed theory of operation; detailed preventive maintenance procedures; detailed calibration and performance checks; detailed trouble shooting; overhaul procedures. Full warranties for all equipment shall remain in place until at least training for the in-house engineer s has been completed. Following the completion of training, the Contractor shall, if requested, certify that trained personnel have completed the Contractor’s training program.

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All In-service and technical service training shall be dedicated to the Company and conducted at the Company's facilities unless otherwise agreed upon. The Contractor at the point of training shall provide the Article. All cost shall be borne by the Contractor.

10.11 The Contractor shall submit full details of system, inclusive of a complete list of options currently available and options that will be available or are currently under development.

10.12 The Company will be entitled to purchase all replacement parts, components, subassemblies and peripheral devices as needed for the maintenance and repair of each model of equipment purchased from the successful Contractor at the fair market price. No excessive handling or shipping charges will be applied to these purchases. The successful Contractor must expedite all shipments and not withhold shipments in order to increase equipment downtime to the Company or for any other reasons.

10.13 The Company has the right to use any service representative of his choosing, including in-house, third party or independent contractor. These representatives have the right to repair, install, calibrate, maintain or overhaul all models of equipment purchased from the successful Tender. The Company's representatives shall be afforded the privilege of ordering all necessary repair parts and components from the successful Contractor for each model of equipment purchased at a fair market price.

10.14 The Tender shall guarantee the availability and sale directly to Company or its representative of spare parts, schematics, parts lists, troubleshooting manuals, operator's instruction manuals, and all other technical data for the life of the equipment and that replacement of defective parts or other equipment maintenance by Company or its representative will not affect warranty conditions.

10.15 The Company has the right to use and operate all hardware and software for the purposes of operating, repairing, or calibrating the equipment. The Company has the right to allow her designated service representative to use all software for the repair and calibration of the equipment purchased.

10.16 The supply of the system computer must be from a registered computer manufacturer and be supported by the manufacturer's service center. The model must fulfill the basic safety requirements of Radio Frequency Interference, Electromagnetic Immunity and Safety for Information Technology Equipment. Proof of safety compliance must be presented during the submission.

10.17 The Company has the right to send her designated service representatives to the manufacturer's service training school to receive sufficient, any or all, technical training to allow the representative to repair and calibrate the equipment purchased.

10.18 All documentation, software and manuals become the sole property of the Company.

10.19 Upon sale or transfer of the equipment purchased within and/or outside of Singapore, the Company's shall have the right to transfer any or all hardware, software, documentation and manuals to the new purchaser of the equipment.

10.20 The Contractor is advice to check for incompleteness and misleading information that may result in disqualification.

10.21 All Contractors are to comply with all requirements stated in the Company Standard Conditions of Contract **- *SCC.3**.

10.22 Failure to comply with any of the above requirements may result in the rejection of the offer.

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*** SCC.3 is available from Material Management Department. All Tenderers are to acquaint themselves with the details requirements set out in SCC.3.**

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A. PERFORMANCE SUMMARY FOR ULTRASONIC BATH

Contractor/Company : _____

Description Of system/Unit : _____

Manufacturer / model : _____

Year of model 1st Sold : _____

Year of manufacture : _____

Country of origin : _____

Warranty period (Min. 2 years) : _____

(The Contractor shall provide a twenty-four (24)-month warranty period, commencing from date of successful completion of commissioning. The Contractor shall replace all original parts including rechargeable battery, provide free labour with unlimited breakdown repair calls and shall also provide regular preventive maintenance as specified in the manufacturer's latest technical manuals or operating manuals during the warranty period at no cost to the Company)

(*Please delete where applicable)

You are advised to be truthful in your submission. Nothing is to be left blank. Where compulsory submissions are required, kindly furnish as required to avoid disqualification.

A Performance Summary must accompany each option offered

No cross-referencing should be used in this performance summary unless specified by the Company.

1.	**FULL COMPLIANT** with technical specifications		* Yes/No
2.	**NON-COMPLIANT** with technical specifications		pls state number only _____ _____ _____
3.	**APPLICATIONS**	pls specify	_____ _____ _____ _____

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4.	**OVERALL SIZE, H, W, D cm** Provide a breakdown for each piece of apparatus if it is not an integrated system.	pls specify	_____ _____ _____
5.	**OVERALL WEIGHT, kg** Provide a breakdown for each piece of apparatus if it is not an integrated system.	pls specify	_____ _____ _____

6. TYPE OF FEATURES

a.	Table Top model .	* Yes/No
b.	Compact design and lightweight	* Yes/No
c.	Simple to operate and easy to maintain	* Yes/No
d.	Fully programmable.	* Yes/No
e.	Air tight containers	* Yes/No
f.	Fully automatic one-button operation.	* Yes/No
g.	Generates high-quality atmospheres in dry conditions.	* Yes/No
i.	Frquency at 38 to 40 kHz	* Yes/No
j.	Capability of removes the biofilm without killing the bacteria.	* Yes/No
j.	Other new enhanced features pls specify	_____ _____ _____

7. Cost saving

a.	Low running costs	*Yes/No
b.	Low maintenance. .	*Yes/No

8. POWER CORD/PLUG

a.	Safety catch for securing the line power cord (casing interface) to the unit casing		* Yes/No
b.	Type of power plug use, e,g.,single phase 13A moulded construction type,etc	pls specify	_____

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9. BATTERY OPERATED (if applicable)

a.	Battery type	pls specify	_____
b.	Battery rating	pls specify	_____
c.	Full charging time	pls specify	_____
d.	Battery operating time, hr	pls specify	_____
e.	Built-in charger		* Yes/No

10. ELECTRICAL SAFETY

a.	Safety Class	pls specify	* I / II / III
b.	Type of protection	pls specify	* B / BF / CF

11. STANDARDS OF COMPLIANCE pls specify _____
(certificates of conformity to be provided)

a.	Can your proposed system comply to International standards such as International Electrotechnical Commission (IEC), British Standards (BS), European Standard (EN), etc?		*Yes/No
b.	Kindly specify the type of compliance and its class.		_____
c.	A certificate for each compliance is required (previous compliance for the same model may be accepted as a reference)		_____
	i) IEC 61010-1, general requirements for electrical for measurements, control and laboratory use or equivalent		* Yes/No
	ii) IEC 61326-1, Electromagnetic Compatibility		* Yes/No
	iii) IEC 61000-4-x series safety requirements and tests for Electromagnetic Compatibility, Immunity		* Yes/No
	iv) IEC 60529 (1989), Degrees of protection provided by enclosures (IP code).		* Yes/No
	- IP code	pls specify	_____
	v) HSA Registration		*Yes/No
	vi) International available standards in the particular requirements for safety and performance for the tendered Article		* Yes/No
	- if yes, pls specify the reference standard		_____
	vii) FDA approval		* Yes/No

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viii) Others (pls specify) _____

*** If certificates for the compliance are not provided during the submission, it shall be considered as non-compliant to the standard.**

12. POWER CONSUMPTION

a. Standby Operation, KVA/KW/Amp pls specify _____

b. Normal Operation, KVA/KW/Amp pls specify _____

c. Heat Dissipation

Equipment	Model	Maximum Heat – Standby Operation	Maximum Heat – Normal Operation

13. WARRANTY & POST-WARRANTY SERVICE CONTRACT (p/s submit with each offer)

_____
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Description	**Warranty Period**	**1st year after warranty**	**2nd year after warranty**	**3rd year after warranty**
Frequency of Preventive maintenance (nos. of times per year)	**Frequency of PM : _____ During Warranty Period /per year**			
Annual Charges for Preventive Maintenance(PM) only. (The cost which covers all labour and transportation cost of providing PM only periodically within a year and corrective maintenance is not included)	**Not Applicable**	**$**	**$**	**$**
Annual Charges for Preventive Maintenance(PM) And unlimited Breakdown Repair calls (The cost which covers all labours transportation, on-site response for providing both PM and corrective maintenance except replacement parts)	**Not Applicable**	**$**	**$**	**$**
Annual Charges for Preventive Maintenance(PM) And unlimited Breakdown Repair calls and all Replacements parts Including software upgrades, etc. (The cost for comprehensive maintenance which covers all labours, transportation, on-site response for providing both PM and corrective maintenance and parts including software upgrades, etc.)	**Not Applicable**	**$**	**$**	**$**

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14. SERVICE SUPPORT

a. Does your service support, irrespective of contracted service or warranty repair covers after office hours i.e. after 5.30 pm and weekends ? * Yes/No

i) After office hours * Yes/No

ii) During weekend * Yes/No

iii) Labour charge for non contract service during office hour $_____/hr

iv) Labour charge for non contract service after office hours $_____/hr

v) Labour charge for non contract service during weekend $_____/hr

**** Please attach operating hours for service support for our information. And provide Sales and Service organisation chart for emergency contract.***

b. What percentage of essential spare part support are you stocking to meet TTSH repair/service needs?

i) percentage of stock essential spare parts relative to *total essential spare parts*. _____ %

ii) cost of stocked items $_____

**** Full list of essential spare parts is required. Kindly indicate those that you would be stocking. Non-stock parts would still be reflected in the full list.***

iii) percentage of stocked essential spare parts relative to the whole system (i.e. all the parts that make up the system) _____ %

c. Please list the TOP 5 most expensive spare part for this unit.

Part No.	Description	Cost (SGD)

d. If parts are to be delivered from overseas, kindly state the turnaround time for delivery to TTSH

i) Standard delivery _____days

ii) Courier delivery _____days

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iii) Air Parcel _____days

iv) Others _____days

e. Number of years spare part will continue to be available after the discontinuation of the model purchased by TTSH _____

f. Frequency of PM (times/year) during warranty period _____

g. 24-hours service available * Yes/No

h. Service response time (hours) _____

i. Maximum down time _____

j. Are your Service Engineer trained on the proposed system? * Yes/No

- Name of trained personnel pls specify _____
- Designation pls specify _____
- Educational qualification pls specify _____
- Contact No/pager for backup services pls specify _____
- Years of service with the employer pls specify _____
- Factory Trained pls specify _____

_____

_____

(If you are not factory trained, please give details of your supervisor or colleague who trained you and supervise your work.)

- Last Training date pls specify _____
- Next Re-certification date pls specify _____

k. Is replacement unit available? * Yes/No

l. Can replacement unit be made available within 24 hours upon request during warranty period? * Yes/No

m. Is the loaner unit available for equipment under repair after warranty period without charges? * Yes/No

If there is charges, what are the charges? _____

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n. Spare Part list (Stocked and Non-stocked items) valid for two (2) years after warranty

S/N	Description	Unit Price	Stock Item Y/N

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15. TRAINING

a. Does your **In-service training** cover:

- equipment operation		* Yes/No
- general maintenance		* Yes/No
- equipment safety verification (for use on patients)		* Yes/No
- others	pls specify	_____
		_____
		_____

b. Does your **technical training** cover:

- installation instructions		* Yes/No
- system overview with block diagram		* Yes/No
- detailed theory of operation		* Yes/No
- detailed preventive maintenance procedures		* Yes/No
- detailed calibration and performance checks		* Yes/No
- detailed trouble shooting		* Yes/No
- overhaul procedures		* Yes/No
- others	pls specify	_____

c. Estimated date for technical training to commence after the delivery of the unit/system. pls specify _____

(Please submit the in-service and technical training programme)

d. Trainer's Credentials

-	Name of Trainer	pls specify	_____
-	Designation	pls specify	_____
-	Educational qualification	pls specify	_____
-	Contact No/pager for backup services	pls specify	_____
-	Years of service with the employer	pls specify	_____

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- Trained by Manufacturer to service product **(Pls submit certificates)** * Yes/No

- Certified by manufacturer to provide technical training **(Pls submit certificates)** * Yes/No

- Date of last technical training received for this product pls specify _____

16. AVAILABILITY OF EVALUATION UNIT * Yes/No

17. AVAILABILITY OF SERVICE MANUALS * Yes/No
(2 X CD of operating/service manual in soft copy for Biomedical Engineering)

18. REFERENCES (LOCAL ONLY)

S/N	**Year Purchased**	**Institution**	**Contact Person/Number**

I hereby certify that all information are true and correct and shall fully comply with all requirements stated in this specifications, unless stated otherwise under the Statement of Non-compliance.

_____
Signature & Stamp/Seal of the Contractor

_____
Name/Designation/Contact No. Date

** Please note that full information shall be provided before the closing date. Insufficient information will not be accepted.

All information must be provided to avoid rejection of offer.

Every page of the Technical & Performance summary must be duly signed and return with the submission.

_____
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ANNEX A-1 COMPLIANCE TO REQUIREMENTS/SPECIFICATION

Please specify in the format below all areas of non-compliance. Failure to use this format may render the Tender submission liable to rejection. **KINDLY REPRODUCE ADDITIONAL COPIES AS NECESSARY.**

Requirements/ Specification Clause No.	Full Details of Non-Compliance

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ANNEX A-2 CONTRACTOR CHECKLIST for **SUBMISSION OF DOCUMENTS**

1. CONFORMITY CERTIFICATES

IMPORTANT: INDICATE "YES" ONLY WHEN DOCUMENTS ARE SUBMITTED!

a.	IEC 60601-1/ IEC 61010-1	* Yes/No
b.	IEC 61000-4-x series or equivalent EMC compliance	* Yes/No
c.	IEC 60601-1-2 or equivalent EMC compliance	* Yes/No
d.	A copy of the HSA registration certificate of the equipment	* Yes/No
e.	Other related	_____
		_____

2. FDA CLEARANCE

a.	Pre-market notification (510K)	* Yes/No
b.	Pre-market approval (PMA)	* Yes/No

3. MANUFACTURER'S LETTER

a.	Distributor appointment letter	* Yes/No

4. PREVENTIVE MAINTENANCE (PM)

a.	Checklist	* Yes/No
b.	Procedure for carrying out PM	* Yes/No

5. SPARE PART PRICE LIST

a.	Full list with price valid for 2 years	* Yes/No
b.	Stocked spare parts	* Yes/No

6. TRAINING PROGRAMME

a.	Detailed Technical training indicating the number of days and the time required for each segment of the training.	* Yes/No

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b. Operator * Yes/No

7. REFERENCE LIST

a. Telephone no/contact person * Yes/No

b. Year in which they were supplied _____

_____

8. PERFORMANCE SUMMARY

a. Fully completed * Yes/No

*(Performance summary is INCOMPLETE without the **SUBMISSION** of documents!)*

9. ORGANISATION CHART * Yes/No

10. CERTIFICATES OF TECHNICAL * Yes/No
SERVICE ENGINEERS

11. OTHERS

_____

_____

_____
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