Andhra Pradesh MedTech Zone Ltd (AMTZ)

Biomedical Equipment Maintenance Certification (BEMC) Scheme

(Certification Body and Accreditation Body requirements)

Contents

1.0 Scope:

This document describes the requirements, of certifying maintenance services and is aimed to give confidence to all interested parties that the service fulfils specified requirements. The value of this certification is to enhance confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified services requirements by a third party.

The requirements mentioned in this document are in addition to the ISO/IEC 17065 and ISO/IEC 17011 as applicable.

2.0 Normative References

- ISO/IEC 17000 - Conformity assessment — Vocabulary and general principles
- ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing evaluation
- ISO/IEC 17065 - Conformity assessment — Requirements for bodies certifying products, processes and services
- ISO/IEC 17011- Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
- Technical Criteria documents for Biomedical Equipment Maintenance Certification Scheme

For all undated references, the latest version of the standard shall be used.

3.0 Terms and definitions

3.1 Accreditation

Third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities

3.2 Impartiality

presence of objectivity

NOTE 1 Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the evaluation body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are: independence, freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

3.3 Client

organization or person responsible to a certification body for ensuring that certification requirements, including applicable maintenance requirements, are fulfilled

3.4 Service

result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally Intangible

NOTE 1 Provision of a service can involve, for example, the following:

a) an activity performed on a customer-supplied Tangible product (e.g. Medical equipment to be repaired /serviced/maintained);
b) the delivery of an Intangible product (e.g., the delivery of information in the context of knowledge transmission).

3.5 Organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

NOTE 1 In the context of Scheme, the organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private related to the maintenance of medical equipment as defined above.

For example, this can be a AMC/CMC service provider, hospital, an individual clinic or Original Equipment Manufacturers (OEM) etc.

NOTE 2 This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

[SOURCE: ISO/IEC TS 17021-4:2013, 3.7]

3.6 Certification requirement

specified requirement, including product requirements that is fulfilled by the client as a condition of establishing or maintaining certification

NOTE Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement to meet this International Standard and can also include requirements imposed on the client by the certification Scheme. “Certification requirements”, as used in this

International Standard, do not include requirements imposed on the certification body by the certification Scheme.

Source: ISO/IEC 17065:2012, 3.7

3.8 Certification Scheme

certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

Source: ISO/IEC 17065:2012, 3.9

3.9 Scope of certification
identification of

- the product(s), process(es) or service(s) for which the certification is granted,
- the applicable certification scheme, and
- the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

Source: ISO/IEC 17065:2012, 3.10

3.10 Scheme owner
person or organization responsible for developing and maintaining a specific certification scheme.

Source: ISO/IEC 17065:2012, 3.11

4.0 Principles of conformity assessment

4.1 Impartiality

4.1.1 Certification activities shall be undertaken impartially.

4.1.2 CB shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.3 CB shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present an CB with a risk to impartiality.

NOTE: A relationship that threatens the impartiality of the CB can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.

4.1.4 The Evaluation process shall be independent from any conflict of interest. This shall be evidenced by the organization structure and risk management records.

4.2. Liability

4.2.1 CB shall have adequate provision (e.g., insurance or reserves) to cover liabilities arising from its operations.

NOTE The liability can be assumed by the State in accordance with national laws, or by the organization of which the CB forms a part.

5.0 Requirements for Certification Body (CB)

5.1 CB shall be a legal entity/a defined part of a legal entity.

5.2 Where the CB is a part of legal entity relationship between the other activities shall be defined to ensure that no conflict of interest exists.

5.3 CB shall maintain a website for providing information about the Scheme and its evaluation activities under the Scheme.

5.4 The organization structure of CB shall demonstrate independence and impartiality.

5.5 CB shall maintain the list of authorized personnel, for handling and management of the requirements under the Scheme. The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

5.6 CB shall have a procedure for determining the competence requirements, selection, training and authorization of all personnel under the Scheme.

5.7 CB shall have a job description or other documentation for each position category within its organization involved in evaluation activities.

5.8 CB shall maintain the following records on the personnel involved in the certification process:

a) name and address;

b) employer(s) and position held;

c) educational qualification and professional status;

d) experience and training;

e) the assessment of competence;

f) performance monitoring;

g) authorizations held within the CB;

h) date of most recent updating of each record.

5.9 The CB shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to the following:

a) to comply with the rules defined by the CB, including those relating to confidentiality and independence from commercial and other interests;

b) to declare any prior and/or present association on their own part, or on the part of their employer, with an operator or developer of processes to the evaluation or certification of which they are to be assigned;

c) to reveal any situation known to them that may present them or the CB with a conflict of interest.

5.10 CBs shall fulfil the competence requirements of the personnel as per Annexure-I, of this document.

5.11 Once the CB is approved by the Scheme owner (AMTZ), the Scheme owner (AMTZ) shall require the CB to sign the agreement form, the template for which is enclosed in Annexure-III of this document.

5.12 CB shall also monitor periodically, the effectiveness of its personnel in a systematic manner.

5.13 CB shall ensure the continued suitability of the instrument (s) used for the purpose of evaluation, if any.

5.14 When the instrument (s) are provided by the organization for the evaluation, the suitability of the same shall be the responsibility of the CB.

5.15 CB shall ensure the data integrity and security for all information stored on computers.

5.16 CB shall review the contract by the organization to perform the work as per this scheme for adequacy and capability. In case there are any deviations in the requirements, the same shall be resolved and accepted by the organization prior to commencement of work, records of all such discussion shall be maintained.

5.17 CB shall not delegate/outsource the certification decisions.

5.18 The CB shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified in the Scheme. Where appropriate, it shall meet the applicable requirements of ISO/IEC 17025 for testing and ISO/IEC 17020 for inspection, considering the applicable impartiality requirements.

5.19 CB may use Personnel who do not have the requisite qualifications as prescribed in this Scheme document provided they are supported by technical experts (TEs) who meet the qualifications as described in Annexure-I of this document. The time spent by the TE on an Evaluation shall not be counted in determining the Evaluation time as prescribed under the ‘certification Process’ which the CB is expected to spend.

5.20 CB shall have rules for the access to, and the use of, instrument (s) used to perform evaluations.

5.28 CB shall be accredited for certification as per the BEMC Scheme covered under ISO/IEC 17065.

6.0 Obligations of the Certification body (CB)

6.1 Before the Organization is certified by the approved CBs, it is desirable to have an agreement detailing the terms and conditions of certification between the CB and organization.

6.2 CB shall be bound by the contract in all the evaluation activities it intends to perform under this Scheme.

6.3 The use of accreditation symbol/mark/status as per policy defined by AMTZ. (Rules for use of Scheme Mark document- AMTZ/BEMCS/SM/R00).

- The use of Scheme logo is permissible only with prior approval from Scheme owner (AMTZ).
- The use of AB symbol/logo is permissible only consequent to accreditation of the CB for the Scheme.

6.4 Change affecting certification

6.4.1 When the certification Scheme introduces new or revised requirements that affect the client, the CB shall ensure these changes are communicated to all clients. The CB shall verify the implementation of the changes by its clients and shall take actions required by the Scheme.

6.4.2 The CB shall inform the Scheme owner (AMTZ of any change within 15 days of the following change as minimum:

a. in the evaluation/evaluation documentation part
b. in the name of the CB
c. in the location of the CB

6.4.3 Under above (6.4.2) circumstances, the Scheme owner (AMTZ) shall review the information/change and may decide to have on site evaluation. If the evaluation is satisfactory, the Scheme owner (AMTZ) shall take appropriate decision on the continuance of the approval.

6.4.4 For any change in Scheme, the Scheme owner (AMTZ) shall inform the approved CB about the transition time available.

6.4.5 The CB shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

6.4.6 The actions to implement changes affecting certification shall include, if required, the following:

- evaluation;
- review;
- decision;
- issuance of revised formal certification documentation to extend or reduce the scope of certification;
- issuance of certification documentation of revised surveillance activities.

7.0 Requirements for Accreditation body (AB)

7.1 ABs shall comply with the requirements of ISO 17011 and shall be an IAF MLA signatory listed in the IAF website.

7.2 AB shall cover the scope (IAF Scope Sectors 18 &19 or equivalent) for ISO 17065 and comply to applicable IAF published documents.

7.3 AB shall meet or fulfil the requirements of this Scheme.

7.4 Within their scope of ISO/IEC 17011, AB shall be IAF MLA Signatory or ISO/IEC 17065.

7.5 AB shall have in-depth knowledge of the Standard(s) for which accreditation is granted. Accreditation activities shall show an understanding of the overall objective of each Standard mentioned in this Scheme, and the requirements of the applicable normative references, and the expertise to audit the particular requirements of approved Standard(s).

7.6 AB shall provide adequate information to demonstrate its related competence (e.g., on assessments performed in relevant scopes, CVs and training protocols of assigned staff).

7.7 For each Standard for which it is authorized, AB shall define any necessary limits (e.g., geographical) to its own operations and shall not take on assessments which it does not have the capacity to complete.

7.8 AB shall establish rules and procedures to prevent or minimize threats of conflict of interest. Any actual or perceived interest in an action that results in or has the appearance of resulting in personal, organizational, or professional gain is considered to be a conflict of interest. In particular,

7.8.1 AB shall require personnel, committee, and board members to declare existing or prior association with an organization being subject to accreditation to ensure that there is no conflict of interest.

7.8.2 If a conflict of interest between accreditation personnel and a CB or an organization is found after an assessment has occurred, another unbiased person shall be assigned to determine if it has affected the accreditation process and to complete the remainder of the process if applicable.

7.8.3 Personnel shall not be allowed to assess their own work.

7.9 Assessors shall meet the minimum qualifications as per Annexure-II of this document.

7.10 AB shall take responsibility for managing the competence of personnel involved in all outsourced activities unless the subcontractor is an approved AB for the applicable Standard(s).

7.11 When acting as a subcontractor for another approved AB, the AB shall take responsibility for conforming with all applicable requirements included in the scope of the sub-contracting and shall not further subcontract services (excluding freelancers).

7.12 When technical experts are used in assessments, the technical experts shall be independent of the CB and (if applicable) the organization being evaluated. The names, qualifications, and affiliations of technical experts shall be included in assessment reports.

ANNEXURE -I

Competence requirement for the CB personnel responsible for the evaluation

CB personnel shall hold a degree from a Government recognized university or technical college in medicine, science, or engineering with a minimum of four years of relevant work experience. Disciplines of interest include, for example:

a) Biology
b) Microbiology
c) Chemistry
d) Biochemistry
e) Computer hardware and software technology
f) Material sciences
g) Engineering in relevant branch
h) Human physiology
i) Medicine
j) Pharmacy
k) Physics and biophysics

The educational requirement shall remain a strong basis for classification of Technical Knowledge. Typically, personnel develop expertise directly related to their educational background. In addition, the Team leader for the evaluation shall be Indian Biomedical Skill Consortium (IBSC) certified professional (Certificate in Biomedical Maintenance (NSQF code- 2019/HLT/AMTZ/3576)) or any certification of international equivalence.

Program manager shall hold a degree from a Government recognized university or technical college in medicine, science, or engineering.

Diploma in the relevant field with minimum five years' experience may be considered as qualifying criteria for both inspecting officer/program manager.

ANNEXURE -II

Knowledge and Skill required for the Accreditation Assessor

In addition to the following knowledge and skill requirement, it is desirable to comply with IAF MD 20.

Identification code for Sub-Category	Assessor
A1	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of legal framework of regulations related to equipment • Knowledge regarding the pressure handling devices
A2	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer
A3	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer

	Note: In case the device falls under Non-active medical devices other than specified above, the CB shall define specific knowledge and skill required.
B1	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant product testing standard (Eg- IEC 60601-1) • Knowledge and Skill of testing equipment such as all kinds of simulator analyser • Knowledge and functional use of safety analyzer
B2	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant product testing standard (Eg- IEC 60601-1) • Knowledge of legal framework of regulations related to equipment • Knowledge regarding the radiation safety • Knowledge regarding the operation of radiation equipment of the product under assessment • Knowledge regarding the image quality parameter (Eg: Phantom based evaluation)
B3	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment

	• Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant product testing standard (Eg- IEC 60601-1) • Knowledge of legal framework of regulations related to equipment • Knowledge and Skill in testing equipment such as all kinds of simulator analyzers • Knowledge and functional use of safety analyzer
B4	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant product testing standard (Eg- IEC 60601-1) • Knowledge of legal framework of regulations related to equipment • Knowledge regarding the radiation therapy safety and performance • Knowledge regarding operation of radiation equipment of the product under assessment • Knowledge regarding the image quality parameter (Eg: Phantom based evaluation)
B5	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant product testing standard (Eg- IEC 60601-1) • Knowledge of legal framework of regulations related to equipment • Knowledge and Skill in testing equipment • Knowledge and functional use of safety

	Note: In case the device falls under Active (non-implantable) medical devices other than specified above, the CB shall define specific knowledge and skill required.
C1	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of legal framework of regulations related to equipment • Knowledge and Skill in testing equipment for IVD • Knowledge and functional use of safety analyzer **Note:** Maintenance may not be required for devices belonging to this category
D1	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the device • Knowledge of ETO sterilization process parameters
D2	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of the autoclave sterilization process parameters

D3	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant sterilization process parameters
D4	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant sterilization process parameters
D5	• Knowledge of medical device risk management (Eg: ISO 14971) • Knowledge of intended use of this subcategory equipment • Knowledge of risk associated with this equipment • Knowledge of legal framework of regulations related to equipment • Control parameter checking knowledge with respect to the manufacturer • Knowledge of relevant sterilization process parameters • Knowledge regarding the radiation safety • Knowledge regarding the operation of radiation equipment of the product under assessment

Annexure-III

Agreement form between the Scheme Owner and Certification Body for the Biomedical Equipment Maintenance Certification (BEMC) Scheme

This agreement is made as of (date) between the Scheme Owner, having its principal office at ____address_____, which expression shall include its successor and assignees and the Evaluation body (Nameof the Evaluation body) having its principal office at_____(address)_____which expression shall include its successors and assignees.

The Applicant (Certification body) hereby applies to Scheme Owner for the approval of the Biomedical Equipment Maintenance Certification **(BEMC**) Scheme at the site(s) specified on the accepted quotation(s) and hereby agrees that such approval shall be based upon and subject to the following:

APPROVAL RULES AND CONDITIONS

1.0 DEFINITIONS. When used in this Agreement the terms listed below have the following meanings:

Applicant:	Evaluation body applying for approval of BEMC Scheme.
Approval:	Decision by Scheme Owner that the CB can do the certification as per this scheme.
Certification body:	body that performs certification activities.

2.0 APPROVAL

An Applicant that is assessed by Scheme Owner and found to meet the specification designated is entitled to hold a Scheme owner approval. The validity of approval shall be as per the accreditation cycle. The approval cannot be transferred or assigned to any other party.

3.0 REQUIREMENTS

3.1 The CB shall, with regard to Scheme Owner:

a. Document and maintain an evaluation process in accordance with the selected Scheme as agreed between the Scheme Owner and CB

b. Inform Scheme Owner in writing of major changes to the evaluation process, evaluation documentation part and any changes relating to the contact address and location, legal,

commercial, organizational status, or ownership, so that the changes may be evaluated by Scheme Owner and action taken as appropriate

c. Allow Scheme Owner, whenever or wherever required, access to all inspected site(s) covered by the CB during normal working hours in order to determine continuing compliance of the Scheme

d. Nominate a management representative and one or two alternates as the point of contact with Scheme Owner

3.2 Scheme Owner shall:

a. Initially review the CB competence and the supporting documentation for compliance with the Scheme.

b. Review the list of authorized personnel, for handling and management of the requirements under the Scheme

c. Maintain all information pertaining to the CB as confidential and not release it to anyone other than AB assessors, Accreditation Body and Regulator if any.

d. In the event receives any complaints relating to the evaluation, the CB shall be notified immediately to take steps as necessary to resolve the issue, including an unscheduled visit to the site.

e. Comply with all applicable rules and regulations made known to them by CB's designated escorts while at CB's site. (Applicant shall not be liable for any loss or injury to Scheme owner personnel sustained while on-premises to conduct assessment activities).

f. Give its CB due notice of any changes to its requirements for this Scheme.

g. When conflicts or diverging opinions regarding evaluation findings or conclusions arise between the evaluation team and the Applicant during an evaluation, CB shall review the request of the organization and take necessary action to resolve the issue.

h. Review the list of technical experts provided if any, for the areas where their own Personnel do not have the requisite qualifications to comply with the Scheme.

4.0 FEES AND EXPENSES

4.1 Fees are defined in the Quotation issued for Biomedical Equipment Maintenance (BEMC) Scheme. Unless otherwise explicitly stated in the contract, all reasonable and customary direct expenses of Scheme Owner Representatives Scheme Owner Representatives required for the performance of the work shall be borne by the Applicant (CB). This includes all expenses related to travel, subsistence, lodging, telephone and any other expenses as governed by the Scheme Owner's Business Travel and Expense Policy. A copy this policy shall be made available to the Applicant upon request.

4.2 All fees are charged in increments of the current daily rate. As and when the fee undergoes a change, the same shall be communicated to all including applicants (CBs) and the certified CB for their acceptance.

4.3 Travel time will be charged as per the agreement between CB and the Scheme Owner.

4.4 Occasionally, findings in an assessment may result in follow-up visits for verification of the resolution to Non-conformities or significant findings prior to the issuance of the approval. The fees for these follow-up assessment, where necessary, shall be invoiced at the current man-day rates considering the time necessary for additional assessment, report review and approval decision.

4.5 In cases where the assessment is terminated prematurely at the request of the CB, there shall be no refund of the amount collected for the particular assignment.

5.0 ASSESSMENT TEAM SELECTION

Assignment of assessors is made by Scheme Owner based on the scope and variety of assignments involved. The CB may request the replacement of an appointed assessor/team member in case of any conflict of interest or any other issues with proper justification in writing.

6.0 ASSIGNMENT

In the performance of the services under the Agreement, Scheme Owner may designate one or more subcontractors (including its affiliated companies) to perform all or part of its duties hereunder, including, but not limited to conducting assessment, invoicing, collection of payment, etc, except decision making.

7.0 APPEALS

If Applicant is aggrieved by any ruling, determination or action of Scheme Owner in any manner relating to approval pursuant to the provisions of the Approval Rules and Conditions, Applicant shall appeal to AB, and such appeals shall be progressed through the CB and ultimately to the management of AB/Scheme owner until resolution is obtained. If resolution cannot be achieved, Applicant may submit the issue to arbitration (see General Terms & Conditions).

8.0 SUSPENSION and WITHDRAWAL

The suspension and withdrawal requirements as defined in certification process document of BEMC Scheme.

9.0 DEFAULT

In the event of a default in performance on the part of the Applicant (CB) or in the event of termination, all documentation, approvals and reports or any property of the Applicant (CB) in possession of Scheme Owner shall be subject to a lien for payment of all fees and expenses due and owing by virtue of this Agreement, the termination hereof, or default hereunder and Scheme Owner will have the right to withhold reports and approvals on any projects for the Applicant (CB).

GENERAL TERMS AND CONDITIONS

1.0 PAYMENT TERMS

1.1 Invoices will be submitted for each event described in the Quotation. All invoices are due and payable upon completion of work.

1.2 CB shall pay to Scheme Owner upon demand the cost of all activities wherever conducted, referred to in this Application, based on Scheme Owner schedule of charges in effect at the time.

2.0 TAXES

In the event that any tax shall become due and payable by virtue of the performance of the services specified hereunder, including any imposition of a value added tax, then the amount of such taxes shall be added to Scheme Owner invoice and shall be paid by the CB in accordance with the terms specified hereunder.

3.0 INDEPENDENT CONTRACTOR

In the performance of the services, hereunder, it is agreed that Scheme Owner is and shall be and remain at all times an independent contractor and that neither Scheme Owner nor any of its officers, employees, servants, agents or subcontractors shall be or act as the employee, servant or agent of the Applicant (CB) in the performance of any of the services.

4.0 ENTIRE AGREEMENT

This Agreement entered into by and between Scheme Owner and the Applicant (CB) constitutes the entire Agreement between the parties. None of the Rules, Terms and Conditions contained herein may be added to, modified, superseded or otherwise altered except by a written instrument signed by an authorized representative of Scheme Owner and the Applicant (CB).

5.0 TERMINATION

Except as otherwise provided herein, this Agreement may be terminated upon the written consent of both parties, or by providing the other party with thirty (30) days' written notice prior to the date of such termination with the exception that accrued fees shall be payable in accordance with the terms hereof.

6.0 ARBITRATION

If Applicant (CB) is aggrieved by any matters relating to the provisions of this Agreement, including those grievances not resolved through Appeals (see Approval Rules and Conditions), Applicant (CB) shall submit the issue to arbitration and such arbitration shall be conducted by three arbitrators to be selected one by each party with the third by the two so chosen and the arbitration to proceed under the Rules of Conciliation and Arbitration of India, such arbitration to take place in Visakhapatnam, Andhra Pradesh, India. The substantive law of the State, the place of Scheme Owner head office will apply to the arbitration with the official language being English.

Scheme Owner agrees to accept such submission. Both parties agree to be bound by the decision of the arbitrators and mutually waive any and all claims to punitive damages in any forum.

7.0 CHOICE OF LAW

The validity, interpretation and performance of this Agreement shall be governed by the Indian laws and in the event of a dispute the parties agree to submit to the jurisdiction of the Andhra Pradesh court, in the State of Scheme Owner head office.

8.0 TIME BAR TO LEGAL ACTION

Any statutes of limitation notwithstanding, Applicant (CB) expressly agrees that its right to bring or assert against Scheme Owner any and all claims, demands, or proceedings whether in arbitration or otherwise, shall be waived unless (a) notice is received by Scheme Owner within ninety (90) days after Applicant (CB) had notice of or should reasonably have been expected to have had notice of the basis for such claims; (b) arbitration or legal proceedings, if any, based on such claims or demands of whatever nature are commenced within one (1) year of the date of such notice to Scheme Owner.

9.0 CONSEQUENTIAL DAMAGES

In no event shall either Scheme Owner or Applicant (CB) be liable for consequential damages, including without limitation, loss of use or loss of profits, incurred by one another or their subsidiaries or successors, regardless of whether such claim is based upon alleged breach of contract, wilful misconduct, or negligent act or omission, of either of them, their employees, agents or subcontractors.

10.0 LIMITATION OF LIABILITY

Any liability raised against the Scheme owner shall be limited to the approval fee received from the client (CB).

11.0 FORCE MAJEURE

Neither party hereto shall be liable to the other for default or delay in performing its obligations hereunder if such default or delay is caused by fire, strike, riot, war, act of God, delay of carriers, governmental order or regulations or any other similar or different occurrence beyond the reasonable control of the party so defaulting or delaying, except that cancellation for such causes may not be made without reimbursement to Scheme owner for expenditures actually incurred for labor and materials upon the authority of this Agreement prior to the transmission of such facsimile, or deposit in the mails of a letter giving such notice PROVIDED ALWAYS that notice of such occurrence is given within seven (7) days after the occurrence.

12.0 NON-WAIVER

No waiver by either party of any breach of any of the terms of the Agreement shall be construed as a waiver of any subsequent breach, whether of the same or of any other term thereof .

The Applicant (CB) hereby applies to Scheme Owner for Approval of the Biomedical Equipment Maintenance Certification Scheme at the site(s) specified on the accepted quotation(s) and hereby agrees that such approval shall be based upon and subject to the Approval Rules & Conditions and General Terms & Conditions.

By _____ **Date** _____

Printed Name _____ **Title** _____

Certification Body _____

Scheme Owner hereby accepts the above Application and agrees to the terms thereof:

By _____ **Date**_____

Printed Name _____ **Title** _____

Annexure-IV

List of Committee Members (Steering Committee and Certification Committee)

COMPOSITION	
Steering Committee Members:	
Chair	
Dr. G.N. Singh	Advisor to Hon'ble Chief Minister-Uttar Pradesh, Former-DCGI, Eminent Expert in Regulatory
Co-Chair	
Mr. Anil Jauhri	Former-CEO, NABCB, Expert in Accreditation Framework
Members	
Mr. Rajiv Nath	Forum Coordinator, Association of Indian Medical Device Industry (AIMED)
Dr. Aparna Dhawan	Executive Director, TIC Council
Dr. Girdhar Gyani	Director General, Association of Healthcare Providers (AHPI)
Dr. Jitendra Kumar Sharma	Managing Director & CEO, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Mrutunjay Jena	Scientist-G, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Dilip Chekuri	CEO, Medi Valley Incubation Council
Mr. N. Venkateswaran	CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL)
Dr. Harish Nadadkarni	Medical Device Expert
Mr. Raj Nathan	President, International Accreditation Services (IAS)
Mr. Ravinder Singh	Senior Scientist, Indian Council of Medical Research (ICMR)
Certification Committee Members:	
Chair	
Mr. Mrutunjay Jena	Scientist-G, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Co-Chair	
Dr. Aparna Dhawan	Executive Director, TIC Council
Members	
Mr. Dimitrios Katsieris	Medical Device Expert, International Accreditation Services (IAS)
Mr. D.S.Tewari	Chairman, Association of Indian Laboratories (AOIL)
Dr. Neeraj Jain	Vice President, Association of Indian Laboratories (AOIL)
Mr. Aaditya Vats	Medical Device Expert, Asia Pacific Medical Technology Association (APACMed)
Mr. V. K. Mediratta	Technical Director, Global Accreditation Bureau (GAB) Qatar
Mr. Shahrukh Khan	Scientist-C, Kalam Institute of Health Technology (KIHT)
Dr. Jaishree Kasliwal	Medical Device Expert
Mr. M.G. Sathyendra	Medical Device Expert
Mr. Manickam	Medical Device Expert