



Andhra Pradesh MedTech Zone (AMTZ)

Address: AMTZ Campus Pragati Maidan VM Steel Project S.O
Visakhapatnam, Pin -530031 Andhra Pradesh - India

APPLICATION FORM FOR PROVISIONAL APPROVAL OF CERTIFICATION BODIES

Biomedical Equipment Maintenance Certification (BEMC) Scheme

Please provide information as per the format and in the space given

SECTION – I		GENERAL INFORMATION			
1.	Name of the Certification Body				
2.	Address of Main Office				
		City			
		State		PIN	
3.	Contact Details	Phone			
		E-mail			
		Web			
4.	Ownership Details (Pvt, Ltd, LLP etc.)				
5.	Legal Registration Details	Status			
		Regn. No.			
		Date of Regn.			
		Regn. Authority			
6.	Address of registered office and Place of Registration*, if any				
		* If registered outside the country where Main Office is located. Also provide above the details of approval to operate or to do business in India / other countries and annex copy of the approval granted.			
7.	Top Management	Name			



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		<i>Designation</i>			
8.	Primary Person Contact	<i>Name</i>			
		<i>Designation</i>			
		<i>Phone</i>			
		<i>Mobile</i>			
		<i>E-mail</i>			
9.	Branch Office Location(s) if any				
		<i>Mention above all Branch Office locations of the Certification Body and annex details as per the format in Table A.</i>			
10	Mention the sub-category code for which the certification body applying for approval (Refer Table C)				

SECTION – II PERSONNEL INFORMATION					
11.	Quality Manager or Management Representative	<i>Name</i>			
12.	Personnel of CB (Specific to BEMC Scheme)	<i>Managerial Staff</i>	<i>Auditors</i>	<i>Support Staff</i>	<i>Total</i>
	Location(s)				
<i>Mention only numbers above and annex details of key Managerial Personnel and all Auditor at the Main Office as well as Branch Office locations (if any pertaining to BEMC Scheme) as per the format in Table B.</i>					



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SECTION – III		OTHER INFORMATION		
13.	a. Accreditation as per ISO/IEC 17065 with Scheme details, if any <i>Please specify Accreditation Cert. No. and Validity Period</i>			
14.	Other Approval(s) from Govt. or Regulatory Bodies, if any			
15.	Other activities within the same legal entity			
16.	Related Organization(s),if any, and their activities			
17.	Major Customer in Medical Industry, if any			
18.	Financial Performance (for last 3 financial years) (As applicable)	<i>Financial Year</i>	<i>Income from Certification</i>	<i>Expenditure</i>



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SECTION – IV DOCUMENTS TO BE SUBMITTED ALONG WITH APPLICATION FORM	
1.	Organization Registration Certificate & Memorandum / Articles of Association (<i>copy only</i>)
2.	Master List of Documents relating to Provisional Approval of CB for BEMC Scheme (<i>with issue and/or revision status</i>)
3.	Quality Manual in accordance with ISO/IEC 17065, if available
4.	Documentation relating to Provisional Approval of CB for BEMC Scheme (Procedures, Competence Criteria of Certification Personnel)
5.	Branch Office(s) to be covered under approval (<i>list as per format in Table – A</i>), if applicable
6.	List of Managerial Personnel & Auditors (list as per format in Table – B)
7.	Application Fee - Amount, Cheque / DD No., Date:
8.	CRM-cum-checklist for Provisional Approval of CBs (as per Scheme Requirements)
9.	Evidence of all qualification, experience and training for certification body managerial personnel & Auditors
10.	Other Documents if any



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SECTION –V

DECLARATION

I, the Authorized Representative on behalf of our Certification Body, agree to the following Terms & Conditions of AMTZ as well as Rules and Procedures for AMTZ Approval under the Provisional Approval of IB for BEMC Scheme, and declare the following:

1. All statements, information and documents provided along with this application are correct to the best of our knowledge and belief.
2. BEMC Scheme criteria, requirements, procedures and documents have been read, understood and implemented.
3. Have adequate resources to undertake certification work under the Provisional Approval of CB for BEMC Scheme, undergo assessment as well as maintain conditions for approval, and shall pay all necessary fee and charges (including any applicable taxes) to AMTZ.
4. Shall always provide, or give access to, all documents, records, information and facilities during the entire assessment process to enable a thorough assessment of our inspection body and also later during the period of approval.
5. Shall take adequate and prompt corrective and/or preventive action(s) as may be necessary on the issues raised by AMTZ.
6. Shall immediately notify AMTZ of any significant changes in organizational status/structure, operations, facilities, main policies, procedures, staff or competence, which are likely to affect our approval.
7. Shall undertake routine assessment, surveillance & reassessment as scheduled by AMTZ and also the verification or surprise visits as decided by AMTZ.
8. Any fee and charges payable by our certification body and which remains unpaid shall be recovered from our certification body with late payment charges as appropriate and decided by AMTZ.
9. Shall ensure that the operations, staff and procedures of our certification body will always continue to comply with the BEMC Scheme requirements and procedures.
10. Shall always maintain impartiality and integrity in operations as well as in certification work.
11. If our certification body at any time is found not complying with the above declaration or the requirements of AMTZ as applicable or is found misrepresenting or misusing approval or carrying out malpractices or bringing AMTZ into disrepute, any action against our certification body may be taken including suspension, withdrawal or debar as deemed appropriate by AMTZ.
12. If any information given along with this application is later found to be false, AMTZ may decide to cancel your application. In such case, the application fee submitted will not be refunded.
13. We shall obtain accreditation from IAFMRA Accreditation Body as per ISO/IEC 17065 within a year from the date of provisional approval by AMTZ.

	Authorized Representative
<i>Signature</i>	
<i>Name</i>	
<i>Designation</i>	
<i>E-mail</i>	
<i>Date</i>	
<i>Place</i>	



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Important Instructions:

To apply for AMTZ Provisional Approval of Certification Bodies for Biomedical Equipment Maintenance Certification (BEMC) Scheme, please complete this application form and send it to AMTZ at the address mentioned below accompanied by:

1. Documents as listed in SECTION IV of application;
2. Application Fee (with applicable taxes) in favour of AMTZ.

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NOTE:

1. Before completing this application, form and submitting application, relevant Provisional approval of CB for Biomedical Equipment Maintenance Scheme documents should be carefully studied. If any clarification is needed, please contact AMTZ.
2. If additional space is required for providing information to any item, the information may be annexed as a separate sheet.

TABLE-A

CERTIFICATION BODY BRANCH OFFICE LOCATION(S)			
S. No.	Branch Office location with complete address	Phone, Fax & E-mail; Local Contact Person (with Designation)	Activities Performed
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			



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TABLE-B

CERTIFICATION BODY MANAGERIAL PERSONNEL & AUDITORS			
S. No.	Name with Designation	Qualifications & Years of Relevant Experience	Location
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Note: Evidences of all qualification, experience and training provided shall be made available for review to the scheme owner AMTZ



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TABLE-C

Sl.No	As per IAF Main Technical Areas as per IAF Main Technical Areas (Category)	As per IAF Technical Areas (SuAs per IAF Technical Areas (Sub-Category))	Identification code for Sub-Category	Product Categories Covered by the Technical Areas as per IAF (Scheme Product Category)	Identification code for Scheme Product Category			
A	Non-active medical devices	General non-active, non implantable medical devices	A1	Non-active devices for anesthesia, emergency, and intensive care	A1-1			
				Non-active devices for injection, infusion, transfusion and dialysis	A1-2			
				Non-active orthopedic and rehabilitation devices	A1-3			
				Non-active medical devices with measuring function	A1-4			
				Non-active ophthalmologic devices	A1-5			
				Non-active instruments	A1-6			
				Contraceptive medical devices	A1-7			
				Non-active medical devices for disinfecting, cleaning, rinsing	A1-8			
				Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies	A1-9			
				Non-active medical devices for ingestion	A1-10			
	Non-active dental devices	A2	Non-active dental devices/equipment and instruments	A2				
	Non-active medical devices other than specified above	A3		A3				
B	Active Medical Devices (Non Implantable)	General active medical devices	B1	Devices for extra-corporal circulation, infusion and haemopheresis	B1-1			
				Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	B1-2			
				Devices for stimulation or inhibition	B1-3			
				Active surgical devices	B1-4			
				Active ophthalmologic devices	B1-5			
				Active dental devices	B1-6			
				Active devices for disinfection and sterilization	B1-7			
				Active rehabilitation devices and active prostheses	B1-8			
				Active devices for patient positioning and transport	B1-9			
				Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies	B1-10			
				Medical gas supply systems and parts thereof	B1-11			
					Devices for imaging	B2	Devices utilizing ionizing radiation Devices utilizing non-ionizing radiation	B2-1 B2-2
					Monitoring devices	B3	Monitoring devices of non-vital physiological parameters Monitoring devices of vital physiological parameters	B3-1 B3-2
					Devices for radiation therapy and thermo therapy	B4	Devices utilising ionizing radiation	B4-1
							Devices utilising non-ionizing radiation	B4-2
		Devices for hyperthermia / hypothermia	B4-3					
	Active (non-implantable) medical devices other than	B5	Devices for (extracorporal) shock-wave therapy (lithotripsy)	B4-4				
				B5				
C	In Vitro Diagnostic Medical Devices (IVD)	IVD Instruments	C1		C1			
D	Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	D1		D1			
		Moist heat	D2		D2			
		Thermic sterilization with dry heat	D3		D3			
		Sterilization with hydrogen peroxide	D4		D4			
		Radiation sterilization (e.g., gamma, x-ray, electron beam)	D5		D5			