INDIAN PHARMACOPOEIA COMMISSION
Materiovigilance Programme of India (IPC-MvPI)
Ministry of Health & Family Welfare, Govt. of India

Sector-23, Raj Nagar, Ghaziabad – 201 002
Tel. No. : 0120-2783392, 2783400, 2783401 Mail : mvpi-ipc@gov.in, lab.ipc@gov.in
Website: www.ipc.gov.in

Format No.:- IPC/MvPI/QSP/004/01/FMT/08

APPLICATION FORM FOR ICMED 9000/ICMED 13485 CERTIFICATION

Registration No. (to be filled by IPC-MvPI)……..

To apply for IPC-MvPI for ICMED* 9000& ICMED 13485, *please complete this application form and send it to IPC-MvPI at the address mentioned above accompanied by:

1. *Documents as listed in Part 11 of application;*
2. *Application Fee (with applicable taxes) in favor of IPC-MvPI.*

Before completing this application form and submitting, relevant ICMED scheme documents available at www.ipc.gov.in should be carefully read. If any clarification is needed, please contact IPC-MvPI.

1. Company Details:

Company Name			
Address of the site to be audited			
		Pin Code	
Mailing Address			
		Pin Code	
Contact Person			
Audit Representative			
Working Hours & Off Days			
Telephone		Extension	
Telefax		E-Mail	
Mobile		Website	
Scope Applied under IPC-MvPI ICMED Scheme	*Level 1 : ICMED 9000* ☐		
	Level 2 : ICMED 13485 ☐		

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2. Company Structure

Legal Form (Pvt. Ltd. etc.)	
Branch offices or plants / subsidiaries /Group Companies	
In India	
In other countries	
As planned to be indicated in the Certificate: i. Address ii. Scope of the Audit	
Main Products	
Main raw materials and supplied parts used or processed	
Core processes	
Outsourced processes	
Last Year's Turnover	
Professional Association Membership	
Major Customers	

3. List allocations to be covered under the Audit Scope (Please List–including Marketing):

Address of Site	Activity To Be Audited	Distance from Major City /Airport and the Main Site

For additional Sites please attach annexure in the format.

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4. No. of Temporary sites* (If applicable mention details including type of activities at this site):

5. Product Specific Legal Requirements:

6. Number of employees in entire company: _____(All shifts = Permanent (Per.) + Casual (Cas.) including unskilled employees)

Employee Information by Units/Shifts

Location	Department	General Shift		Shift I		Shift II		Shift III	
		Permanent	Casual	Permanent	Casual	Permanent	Casual	Permanent	Casual
Unit 1	Administration/ Mktg./ Others								
	Design								
	Production (Incl. Quality)								
	Unskilled employees								
Unit 2	Administration/ Mktg./ Others								
	Design								
	Production (Incl. Quality)								
	Unskilled employees								
	Total								

For additional sites please attach annexure in the same format.

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7. Which of the following technical areas best describe your organization?

Non-Active Medical Devices	
☐ General non-active, non-implantable medical devices	
☐ Non-active implants	
☐ Devices for wound care	
☐ Non-active dental devices and accessories	
☐ Non-active medical devices other than those specified above (please specify device category):	
In-vitro Diagnostic Medical Devices (IVD)	
☐ Reagents and reagent products, Microbiology, Infectious Immunology	
Sterilization Methods for Medical Devices	
☐ Ethylene Oxide Gas sterilization (EOG)	☐ Moist Heat
Describe what your organization does as a manufacturer and/or service provider	
Are there any employees that you did not include in the above-mentioned table because you consider them to be outside the scope of the audit?	☐ Yes ☐ No If yes, please explain:
Who designs the products /services that you provide to your customer?	Check all that apply: ☐ Customers provide product designs that we produce ☐ We design our own products at the site to be certified. ☐ Our company designs products at another location that we produce at the site to be certified. ☐ We outsource design activities to suppliers / subcontractors. ☐ We are a distributor of products that are designed and manufactured by another company.

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Do employees in all shifts do similar activities: ☐ Yes ☐ No ☐ Not applicable?

- What Functions are performed centrally (Marketing, Purchasing, etc)?

  _____

  _____

  _____

  _____

- Have consultancy services or in-house training been performed on the subject of ICMED 9000/ ICMED13485/ ISO14971/ any other related training?

  If yes, by whom and when were they performed? _____

- Do you have a Quality Management System manual for the entire group? ☐ Yes ☐ No ☐ Not applicable
- Are the manuals of the subsidiaries based on the group manual? ☐ Yes ☐ No ☐ Not applicable
- Does the company have any other valid certificates? If yes, please provide details-.

8. The audit should be based on the following standards:

☐ ICMED13485(with/without design)	☐ ICMED 9000+ICMED13485 (with/without design)	☐ ICMED 9000(with/without design)

9. Any Significant changes (from the last audit)? (Applicable only for Re-certification, Surveillance, and Expansion Audits)

☐ Yes ☐ No (If yes, mention the details)

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10. PERSONNEL INFORMATION

1.	**Quality Manager**		*Name*		
2.	**Personnel for ICMED Scheme**		*Managerial Staff*	*Support Staff*	*Total*
	Location(s)				
	Mention only numbers above and annex details of key Managerial Personnel at the main office as well as branch office locations as per the format in Table B.				

11. ANNEXED INFORMATION

1.	Organization Registration Certificate & Memorandum/Articles of Association (*copy only*)	*Annex* –**1**
2.	Master List of Documents relating to ICMED (*with issue and/or revision status*)	*Annex* –**2**
3.	Quality Manual in accordance with ISO 13485:2016	*Annex* –**3**
4.	Documentation relating to ICMED (Procedures, Competence Criteria, Formats, Checklists etc.)	*Annex* –**4**
5.	Branch Office(s) to be covered under approval (*list as per format in Table–A)*	*Annex* –**5**
6.	a) Copy of a facility lay out with the identity of all manufacturing areas and process flow chart. b) Copy of the organization chart and company's product brochures. c) `List of Medical Device, Device master file, Design & Development file, Risk Management file, Preclinical and Clinical reports/data, Post marketing surveillance & Vigilance, and Post marketing clinical follow-up etc, Essential principles of safety and performance, Biocompatibility, Pre-clinical and clinical expertise, Software validation etc.	*Annex* –**6**
7.	Application Fee -*Amount, NEFT/ RTGS, Date*:	*Annex* –7
8.	Other Documents (*annex list*)	*Annex* **–8**
9.	List of products	*Annex* **- *9***

12. DECLARATION

The authorized representative of clients agree to the following terms & conditions of IPC-MvPI as well as Rules and Procedures for IPC-MvPI approval under the ICMED Scheme, and declare the following:

1. All statements, information and documents provided along with this application are correct to the best of knowledge and belief.
2. IPC-MvPI certification criteria, requirements, procedures and documents have been read, understood and implemented.
3. Have adequate resources to undertake QMS or medical devices certification work under the respective ICMED schemes, undergo assessment as well as maintain conditions for approval, and shall pay all necessary fee and charges (including any applicable taxes) to IPC-MvPI.
4. Shall ensure that the operations, staff, and procedures always continue to comply with the ICMED Scheme requirements and procedures.
5. Shall always maintain impartiality and integrity in operations.
6. Shall always provide, or give access to, all documents, records, information, and facilities during the entire assessment process to enable a thorough assessment of client and also later during the period of approval.
7. Shall take adequate and prompt corrective and /or preventive action(s) as may be necessary on the issues raised by IPC-MvPI.
8. Shall immediately notify IPC-MvPI of any significant changes in organizational status/structure, operations, facilities, main policies, procedures, staff or competence, which are likely to affect our approval/renewal.
9. Shall provide the previous evaluation report to IPC-MvPI, if they have been registered with any other certification body.
10. Shall declare any judicial proceedings relating to its operations, any proceedings by any regulatory body or suspension/cancellation/withdrawal of any certification/approval under any regulation or otherwise.
11. Shall undertake routine assessments, surveillances & reassessments as scheduled by IPC-MvPI and also the verification or surprise visits as decided by IPC-MvPI.
12. Any fee and charges payable by our clients and which remains unpaid shall be recovered from our Clients with late payment charges as appropriate and decided by IPC-MvPI.
13. If our clients at any time is found not complying with the above declaration or the requirements of QCI or the ICMED 9000 or/ and ICMED 13485 standard as applicable or is found misrepresenting or misusing approval or carrying out malpractices or bringing IPC-MvPI into disrepute, an action against client may be taken including suspension, withdrawal or debar as deemed appropriate.
14. If any information given along with this application is later found to be false, IPC-MvPI may decide to cancel application.

Name	Designation	Mobile No./ E-mail	Date	Place	Signature with company stamp

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TABLE-A

CLIENT BRANCH OFFICE DETAILS					
Sl. No.	**Branch office location with complete address**	**Activities performed**	**Primary contact person**	**Designation**	**Phone, Fax & E-mail**

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TABLE-B

CLIENT MANAGERIAL PERSONNEL COMPETENCIES				
S. No.	**Name**	**Designation**	**Qualification**	**Relevant Experience (Years)**