CERTIFICATION APPLICATION FORM

Quality Management System: ISO 13485: 2016 Medical Devices

Note : *This application Form should be completed and submitted by the Authorised Representative of the applicant organisation.*

FORM MATRIX

Section A	Organisation Information	Mandatory	Jump to SECTION A
Section B	Site Information	Mandatory	Jump to SECTION B
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Section F	Terms and Conditions	Mandatory	Jump to SECTION F

Section A: Organisation Information

Section A1: Regustration Information of the organisation

Company Name:	
Trading Name:	
Company / Organisation Type:	Close Corporation
Reg. No	
Attach Reg. Certificate with Submission	Yes
VAT. No	

Section A2: SAHPRA Licence information

Registered Wholesaler	No	SAHPRA Licence Number	
Registered Manufacturer	No	SAHPRA Licence Number	
Registered Distributer	No	SAHPRA Licence Number	

Section A3: Contact Detail of the Organisation

Contact Numbers:	**Tel:**	
	Fax:	
Website:		
Mailing Address	**Street Address**	
	City	
	Province/State	
	Country	
	Postal/ Zip Code	

Section A4: Key Personal Detail

Company CEO/MD:	Name:	
	Position:	
	Phone number:	
	Email address:	
Authorised Representative:	Name:	
	Position:	
	Phone number:	
	Email address:	
Accounts Payale Contact Details:	Name:	
	Position:	
	Phone number:	
	Email address:	

Section A5: Certification Services Required.

Which Service do you wish to apply for	ISO 13485:2016

SECTION B: SITE INFORMATION (WHERE AUDITS WILL TAKE PLACE)

Section B1: MAIN SITE

No. of Employees at Site		
Activities at the Site	Wholesalling	
Location	Street Address:	
	City:	
	Province/State:	

	Postal/ Zip Code:	
	Country:	
Contact Person:	Name	
	Position:	
	Phone number:	
	Email address:	

If Yes, Please Complete the following details

Does the organisation have more than 3 site to be included as part of certification audit ? No

Section B2: Additional Site 1

Does the entity have - Additional Site 1		
No. of Employees at Site		
Activities at the Site	Distribution	
Location	Street Address:	
	City:	
	Province/State:	
	Postal/ Zip Code:	
	Country:	
Contact Person:	Name	
	Position:	
	Phone number:	
	Email address:	

Section B3: Additional Site 2

Does the entity have - Additional Site 2		
No. of Employees at Site		
Activities at the Site	Distribution	
Location	Street Address:	
	City:	
	Province/State:	
	Postal/ Zip Code:	
	Country:	
Contact Person:	Name	
	Position:	
	Phone number:	
	Email address:	

Section B4: Additional Site 3

Does the entity have - Additional Site 3		
No. of Employees at Site		
Activities at the Site	Distribution	
Location	Street Address:	
	City:	
	Province/State:	
	Postal/ Zip Code:	
	Country:	
Contact Person:	Name	
	Position:	
	Phone number:	
	Email address:	

Section B5: Additional Site 4

Does the entity have - Additional Site 4		
No. of Employees at Site		
Activities at the Site	Distribution	
Location	Street Address:	
	City:	
	Province/State:	
	Postal/ Zip Code:	
	Country:	
Contact Person:	Name	
	Position:	
	Phone number:	
	Email address:	

How many **Additional Sites** are to be audited over and above the ones mentioned above ?

SECTION C: MANAGEMENT SYSTEM INFORMATION

1. **Type of audit to be conducted ?** Special Audit
2. **When do you expect the management system to be ready for the audit ?**
3. **Is a Management Review conducted ?** No
4. **Is the system you are seeking assessment for integrated with any other management system ?** *If Yes; Provided details* No
5. **Is an internal audit conducted?** No

6. **Do you currently have any other management system certified by any other Certification body** — Yes

If Yes; Please provide the following

Certification Body	Standard	Scope	Ceritifiocation No.

If Yes; Provide the Name and contact details of the Consultant

7. **Have you used a Consultant to develop and implement your System** — No

8. **Is any process used by the organisation outsourced** — No

If Yes; Please provide the following

i
ii
iii
iv
v

9. **Is the last audit report available with outstanding non-conformities** — No

10. **Any complaints received from customers or other parties** — No

11. **Any current engagement by the organisation with regulatory bodies in respect of legal compliance** — No

12. **Any technological and regulatory context IBRATSA needs to take into consideration?** — No

13. **Indicate the Language of communication for all employees in the organisation**

14. **Where did you hear about IBRATSA** — Website — *If other; Please provide the details*

SECTION D: GENERAL BUSINESS INFORMATION ISO 13485:2016

1. **For each medical device category, please answer Question 1 to 4 in clounm H to colomn O.**

Medical Devices Technical Areas	Use a Yes or No to indicate products that you handle in your organisation.
A. NON-ACTIVE MEDICAL DEVICES:	No
GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES	No
NON-ACTIVE IMPLANTS	No
DEVICES FOR WOUND CARE	No
NON-ACTIVE DENTAL DEVICES AND ACCESSORIES	No
B. ACTIVE MEDICAL DEVICES (NON-IMPLANTABLE)	No
GENERAL ACTIVE MEDICAL DEVICES	No
DEVICE FOR IMAGING	No
MONITORING DEVICES	No
DEVICES FOR RADIATION & THERMOS THERAPY	No
C. ACTIVE IMPLANTABLE MEDICAL DEVICES	No
GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES	No
D. MEDICAL DEVICES INCORPORATING SPECIFIC SUBSTANCES OR TECHNOLOGIES	No
E. IN-VITRO MEDICAL DEVICES (IVDS)	No
F. MEDICAL DEVICES OTHER THAN SPECIFIED ABOVE	No — *If Yes; Please provide the details*

2. **Does your organisation use the following Sterilization Methds for Medical Devices** — Yes

If your answer is YES, which methods as defines are provided

Ethylene oxide gas sterilization (EOG)	No
Moist heat	No
Aseptic processing	No
Radiation sterilization (e.g., gamma, x-ray, electron beam)	No
Low temperature steam and formaldehyde sterilization	No
Thermic sterilization with dry heat	No
Sterilization with hydrogen peroxide	No
Sterilization method other than specified above	No — *If Yes; Please provide the details*

3. **Does your organisation provide the following part or services?** — No

If your answer is YES, which services or part as defines are provided

Technical Areas

Raw materials	e.g. Raw metals, plastic, wood, ceramic	No
Components	e.g. Electrical components, fasteners, shaped raw materials, machined raw materials, and molded plastic	No
Subassemblies	e.g. Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions	No

Calibration service	e.g. Verification/confirmation services for measuring instruments, tools, or test fixtures	No	
Distribution service	e.g. Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.	No	
Maintenance servi	e.g. Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.	No	
Transportation ser	e.g. Trucking, shipping, air transportation service in general.	No	
Other services	e.g. Consulting services related to medical devices, packaging services, etc.	No	*If Yes; Please provide the details*

4. Please write down the Scope of Certification that your organisation is seeking

SECTION E: OCCUPATIONAL HEALTH AND SAFETY INFORMATION

Please indicate through the following checkboxes any special details regarding safety whilst at your premises:

1.	There are no industry-specific safety risks or equipment applicable	No
2.	We will supply all other PPE	No
3.	The following Personnel Protective Equipment (PPE) is required to be supplied by the auditor: Safety Shoes Only	No
4.	A safety induction is required for entry into the premises/site(this time is additional to any audit duration)	No

If option 3 and/or 4 is checked above, please explain Personnel Protective Equipment (PPE) and/or safety induction process required

SECTION F: TERMS AND CONDITIONS

1.	**The applicant warrants that the information provided in this application form is accurate and correct.**	No
2.	**The signing of the application form places no obligation on the applicant to pay any auditing fees and the information provided in this application is purely used to compile a quotation/service level agreement.**	No
3.	**The applicant acknowledges that it has read and agrees to abide by the contractual terms contained in the following documents available on our website:** i) IBRATSA Terms and Conditions for Certification. ii) Certification process. iii) Use of Certification Symbols	No
4.	**The applicant agrees that if IBRATSA issues a Certificate, the applicant will use the IBRATSA Certification Symbol in accordance with the Certification Scheme Terms.**	No
5.	**This application remains valid for <u>six</u> months from the date at which the application was made, after which period, the application will expire and a new application will have to be submitted.**	No
6.	**The applicant agrees that this application has been signed without prejudice or pressure from external parties.**	No

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Staff Compliment Information (where audits will take place)

Department	NUMBER OF EMPLOYEES					Total Number of Employees per Department
	Main Site	Additional Site 1	Additional Site 2	Additional Site 3	Additional Site 4	
Management						
Finance						
Production						
Maintenance						
Quality Control / Assurance						
Human Resources						
IT/Technology						
Receiving and Dispatch						
Wharehouse						
Customer Service/Sales						
Other (specify)						
Total Employees per Site						

Shift Staff Compliment (where audits will take place)

Department	Main Site		Additional Site 1		Additional Site 2		Additional Site 3		Additional Site 4	
	Number of shift Employees	Shift hours	Number of shift Employees	Shift hours	Number of shift Employees	Shift hours	Number of shift Employees	Shift hours	Number of shift Employees	Shift hours
Management										
Finance										
Production										
Maintenance										
Quality Control / Assurance										
Human Resources										
IT/Technology										
Receiving and Dispatch										
Wharehouse										
Customer Service/Sales										
Other (specify)										
Total Employees per Site										

Signature of Responsible person

Designation

Date

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History of Document Changes

Rev No./ Issue No.	Date dd/mm/yy	Description of Changes	State (Approved / Not Approved)	Change Initiator (Initials)	New Rev No./ Issue No.
0/1	9/20/2001	Initial Release	Approved	FM	0/1
0/1	6/29/2022	Application form was revised and additional questions added	Approved	FM	0/2
0/2	7/11/2022	Transfer Application form was updated and cheanged from Word to Excel.	Approved	AM	0/3
0/3	1/17/2023	Amend Section D to align with the new MD9:2022.	Approved	AM	0/4
0/4	10/6/2024	New Rev/Issue as part of the Re-coding and re-structuring of the QMS documents. Revision of relevent in-text.	Approved	FM	1/1
1/1	17/07/2024	Added the "Management" category on the staff complement		AM	1/2