

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

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Section B	Site Information	Mandatory	Jump to SECTION B
Section C	Management System Information	Mandatory	Jump to SECTION C
Section D	General Business Information ISO 13485:2016	Mandatory	Jump to SECTION D
Section E	Occupational Health and Safety Information	Mandatory	Jump to SECTION E
Section F	Terms and Conditions	Mandatory	Jump to SECTION F

Section A: Organisation Information

Section A1: Registration Information of the organisation

Company Name:	<input type="text"/>
Trading Name:	<input type="text"/>
Company / Organisation Type:	<input type="text"/>
Reg. No	<input type="text"/>
Attach Reg. Certificate with Submission	<input type="text"/>
VAT. No	<input type="text"/>

Section A2: SAHPRA Licence information

Registered Wholesaler	<input type="text"/>	SAHPRA Licence Number
Registered Manufacturer	<input type="text"/>	SAHPRA Licence Number
Registered Distributer	<input type="text"/>	SAHPRA Licence Number

Section A3: Contact Detail of the Organisation

Contact Numbers:	Tel:	<input type="text"/>
	Fax:	<input type="text"/>
Website:	<input type="text"/>	
Mailing Address	Street Address	<input type="text"/>
	City	<input type="text"/>
	Province/State	<input type="text"/>
	Country	<input type="text"/>
	Postal/ Zip Code	<input type="text"/>

Section A4: Key Personal Detail

Company CEO/MD:	Name:	<input type="text"/>
	Position:	<input type="text"/>
	Phone number:	<input type="text"/>
	Email address:	<input type="text"/>
Authorised Representative:	Name:	<input type="text"/>
	Position:	<input type="text"/>
	Phone number:	<input type="text"/>
	Email address:	<input type="text"/>
Accounts Payable Contact Details:	Name:	<input type="text"/>
	Position:	<input type="text"/>
	Phone number:	<input type="text"/>
	Email address:	<input type="text"/>


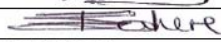
Section A5: Certification Services Required.

Which Service do you wish to apply for	<input type="text"/>
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SECTION B: SITE INFORMATION (WHERE AUDITS WILL TAKE PLACE)

Section B1: MAIN SITE

No. of Employees at Site	<input type="text"/>	
Activities at the Site	<input type="text"/>	
Location	Street Address:	<input type="text"/>
	City:	<input type="text"/>
	Province/State:	<input type="text"/>

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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 ?

Section B: Additional Site 1

Does the entity have - Additional Site 1

No. of Employees at Site

Activities at the Site

Location: Street Address:

City:

Province/State:

Postal/ Zip Code:

Country:

Contact Person: Name

Position:

Phone number:

Email address:

Section B: Additional Site 2

Does the entity have - Additional Site 2

No. of Employees at Site

Activities at the Site

Location: Street Address:

City:

Province/State:

Postal/ Zip Code:

Country:

Contact Person: Name

Position:

Phone number:

Email address:

Section B: Additional Site 3

Does the entity have - Additional Site 3

No. of Employees at Site

Activities at the Site

Location: Street Address:

City:

Province/State:

Postal/ Zip Code:

Country:

Contact Person: Name

Position:

Phone number:

Email address:

Section B: Additional Site 4

Does the entity have - Additional Site 4

No. of Employees at Site

Activities at the Site

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 ?


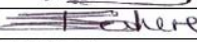
2. When do you expect the management system to be ready for the audit ?

3. Is a Management Review conducted ?

4. Is the system you are seeking assessment for integrated with any other management system ?

5. Is an internal audit conducted?

If Yes; Provided details

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

If Yes; Please provide the following

Certification Body	Standard	Scope	Certification No.

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

7. Have you used a Consultant to develop and implement your System

8. Is any process used by the organisation outsourced

If Yes; Please provide the following

i	
ii	
iii	
iv	
v	

If yes, are the outsourced processes integral to your business operations?

Please describe the level of control your organization exercises over these outsourced processes:

9. Is the last audit report available with outstanding non-conformities

10. Any complaints received from customers or other parties

11. Any current engagement by the organisation with regulatory bodies in respect of legal compliance

12. Any technological and regulatory context IBRATSA needs to take into consideration?

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

14. Where did you hear about IBRATSA

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:

GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
NON-ACTIVE IMPLANTS
DEVICES FOR WOUND CARE
NON-ACTIVE DENTAL DEVICES AND ACCESSORIES

B. ACTIVE MEDICAL DEVICES (NON-IMPLANTABLE)

GENERAL ACTIVE MEDICAL DEVICES
DEVICE FOR IMAGING
MONITORING DEVICES
DEVICES FOR RADIATION & THERMOS THERAPY

C. ACTIVE IMPLANTABLE MEDICAL DEVICES

GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES

D. MEDICAL DEVICES INCORPORATING SPECIFIC SUBSTANCES OR TECHNOLOGIES

E. IN-VITRO MEDICAL DEVICES (IVDS)

F. MEDICAL DEVICES OTHER THAN SPECIFIED ABOVE

If Yes; Please provide the details

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

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

Ethylene oxide gas sterilization (EOG)
Moist heat
Aseptic processing
Radiation sterilization (e.g., gamma, x-ray, electron beam)
Low temperature steam and formaldehyde sterilization
Thermic sterilization with dry heat
Sterilization with hydrogen peroxide
Sterilization method other than specified above

If Yes; Please provide the details

3. Does your organisation provide the following part or services?


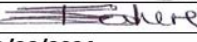
If your answer is YES, which services or part as defines are provided

Technical Areas

Raw materials e.g. Raw metals, plastic, wood, ceramic

Components e.g. Electrical components, fasteners, shaped raw materials, machined raw materials, and molded plastic

Subassemblies e.g. Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions

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Calibration service e.g. Verification/confirmation services for measuring instruments, tools, or test fixtures

Distribution service e.g. Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.

Maintenance service e.g. Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.

Transportation service e.g. Trucking, shipping, air transportation service in general.

Other services e.g. Consulting services related to medical devices, packaging services, etc.

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


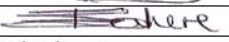
Please indicate through the following checkboxes any special details regarding safety whilst at your premises:

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

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

- The applicant warrants that the information provided in this application form is accurate and correct.
- 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.
- The applicant acknowledges that it has read and agrees to abide by the contractual terms contained in the following documents available on our website:
 - IBRATSA Terms and Conditions for Certification.
 - Certification process.
 - Use of Certification Symbols
- The applicant agrees that if IBRATSA issues a Certificate, the applicant will use the IBRATSA Certification Symbol in accordance with the Certification Scheme Terms.
- This application remains valid for six 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.
- The applicant agrees that this application has been signed without prejudice or pressure from external parties.

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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										

Please note that our audits may be conducted either onsite or remotely using Information and Communication Technology (ICT) tools to ensure effective and efficient auditing and certification processes. By signing this form, you agree to the use of ICT tools, such as video conferencing, document sharing platforms, and other digital means, for the purposes of conducting audits and facilitating certification.


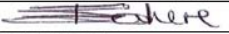
Do you agree to the use of ICT in the auditing and certification processes?

If no, please specify any concerns or limitations:

Signature of Responsible person

Designation

Date

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