

## CERTIFICATION APPLICATION FORM

### Quality Management System: ISO 9001:2015 and 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	<a href="#">Jump to SECTION A</a>
Section B	Site Information	Mandatory	<a href="#">Jump to SECTION B</a>
Section C	Management System Information	Mandatory	<a href="#">Jump to SECTION C</a>
Section D	General Business Information ISO 13485:2016	Mandatory	<a href="#">Jump to SECTION D</a>
Section E	General Business Information ISO 9001:2015	Mandatory	<a href="#">Jump to SECTION E</a>
Section F	Occupational Health and Safety Information	Mandatory	<a href="#">Jump to SECTION F</a>
Section G	Terms and Conditions	Mandatory	<a href="#">Jump to SECTION G</a>

#### 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

If applying for certification of both Schemes, Please complete both SECTION D and SECTION F

#### 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"/>

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Contact Person:	City:	<input type="text"/>
	Province/State:	<input type="text"/>
	Postal/ Zip Code:	<input type="text"/>
	Country:	<input type="text"/>
	Name:	<input type="text"/>
	Position:	<input type="text"/>
	Phone number:	<input type="text"/>
	Email address:	<input type="text"/>

Does the organisation have more than 3 site to be included as part of certification audit ?

If Yes, Please Complete the following details

## Section B: Additional Site 1

Does the entity have - Additional Site 1	<input type="text"/>
No. of Employees at Site	<input type="text"/>
Activities at the Site	<input type="text"/>
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	<input type="text"/>
No. of Employees at Site	<input type="text"/>
Activities at the Site	<input type="text"/>
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	<input type="text"/>
No. of Employees at Site	<input type="text"/>
Activities at the Site	<input type="text"/>
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	<input type="text"/>
No. of Employees at Site	<input type="text"/>
Activities at the Site	<input type="text"/>
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 ?





If Yes; Provided details

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5. Is an internal audit conducted?

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.

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

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

8. Is any process used by the organisation outsourced

If Yes; Please provide the following

i	
ii	
iii	
iv	
v	

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 Yes; 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 column H to column 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 &amp; 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 Methods 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

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Subassemblies	e.g. Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
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: GENERAL BUSINESS INFORMATION ISO 9001:2015

1. For each ISO 9001 Technical Cluster, please answer Question 1 to 4 in clounm H to colomn O.

#### QMS (ISO 9001) Scopes of Certification

1. Use a Yes or No to indicate products that you handle in your organisation

##### FOOD

Agriculture, forestry and fishing  
Food products, beverages and tobacco  
Hotels and restaurants

##### MECHANICAL

Basic metals and fabricated metal products  
Machinery and equipment  
Electrical and optical equipment  
Shipbuilding  
Other transport equipment

##### PAPER

Limited to "Paper products"  
Publishing companies  
Printing companies

##### MINERALS

Mining and quarrying  
Non-metallic mineral products  
Concrete, cement, lime, plaster, etc.

##### CONSTRUCTION

Construction  
Engineering services

##### GOODS PRODUCTION

Textiles and textile products  
Leather and leather products  
Wood and wood products  
Rubber and plastic products  
Manufacturing not elsewhere classified

##### CHEMICALS

Limited to "Pulp and paper manufacturing"  
Manufacture of coke and refined petroleum products  
Chemicals, chemical products and fibres

##### SUPPLY

Electricity supply  
Gas supply  
Water supply

##### TRANSPORT AND WASTE MANAGEMENT

Recycling  
Transport, storage and communication  
Other social services

##### SERVICES

Wholesale and retail trade; Repair of motor vehicles,motorcycles and personal and household goods  
Financial intermediation; real estate; renting  
Information technology  
Other services  
Public administration  
Education

##### NUCLEAR

Nuclear fuel

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PHARMACEUTICAL

Pharmaceuticals

AEROSPACE

Aerospace

HEALTH

Health and social work


## SECTION F: OCCUPATIONAL HEALTH AND SAFETY INFORMATION

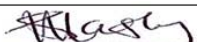

Please indicate through the following checkboxes any special details regarding safety whilst at your premises:

- 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 G: 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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### Section B2 : Site 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						
Warehouse						
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										
Warehouse										
Customer Service/Sales										
Other (specify)										
Total Employees per Site										

Signature of Responsible person

Designation

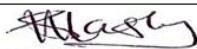

Date

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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 changed 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 category "Management" to staff complement	Approved	AM	1/2

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