ISO 13485 APPLICATION FORM

THANK YOU FOR CHOOSING JCA

We believe in building trusted relationships through exceptional service and appreciate the opportunity to quote on your ISO/SANS certification requirements. We hope this marks the beginning of a long and fruitful partnership.

SECTION 1

Kindly tell us more about your organisation

Company Name _____

Registration Number _____

VAT Number _____

Physical Address _____

_____

Telephone Number _____

Authorised Representative Details

Representative Name _____

Designation/Title _____

Email Address _____

Contact Number _____

Judah Compliance Auditors CC,
Block D, Suite 12, Hilltops Office Park,
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Type of Application

☐ Initial Application ☐ Extension of Scope ☐ Recertification ☐ Transfer of Certification

SECTION 2

Management System Information

Does the company have any of its processes outsourced? Yes ☐ No ☐

If yes, specify :

Is the company certified to any other standard? Yes ☐ No ☐

If yes, specify :

☐ RTMS SANS 1395-1 ☐ ISO 22000
☐ ISO 9001 ☐ ISO 13485
☐ ISO 14001 ☐ ISO 3834
☐ ISO 45001 ☐ Other:

Are systems integrated? Yes ☐ No ☐

Did the company use a consultant? Yes ☐ No ☐

If yes, specify :

Audit Scope & Company Processes

Audit Scope :

Target date for audit :

Products/Services Provided :

Subcontracted Activities :

Language used during audit :

Translator required for the audit : Yes ☐ No ☐

Any specific cultural requirements : Yes ☐ No ☐

If yes, specify :

Any additional information :

SECTION 3

Transfer of Certification *(only applicable for transfer of certification)*

Current certification body :

Transfer planned with current certification cycle ☐ Transfer planned at recertification ☐

Recertification date :

Reasons for transfer :

■ *Please provide certificate and audit reports from previous audits (including non-conformances) with previous certification body.*

SECTION 4

Are all functions centrally managed by head office? Yes ☐ No ☐

How many sites will be certified in total:

Head Office *(Main Site)*

Site Address

Effective personnel

SAHPRA License : Yes ☐ No ☐

SAHPRA License Number :

License Type / Activities:

Manufacturer ☐

Distributor ☐

Wholesaler ☐

Medical Device Category

☐ Class A ☐ Class B ☐ Class C ☐ Class D

*Note: Kindly provide a copy of your SAHPRA license

Multi-Site

No.	Site Address	Effective Personnel	SAHPRA License No.	Activities/Scope	Device Category
1.				Choose Scope	Choose Class
2.				Choose Scope	Choose Class
3.				Choose Scope	Choose Class
4.				Choose Scope	Choose Class
5.				Choose Scope	Choose Class
6.				Choose Scope	Choose Class
7.				Choose Scope	Choose Class
8.				Choose Scope	Choose Class
9.				Choose Scope	Choose Class
10.				Choose Scope	Choose Class

Thank you for taking the time to complete our application form

SUBMIT

Form submitted successfully. Thank you for your response

Our team of medical device experts will gladly assist with any further information or guidance required

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