

## **1. INTRODUCTION**

1.1 These Standard Terms and Conditions ("Terms") govern the relationship between **Africa Healthcare Holdings (Pty) Ltd** ("Afrihealth", "we", "us", or "our") and any client ("Client", "you", or "your") who engages Afrihealth for professional services, including those as a medical device **Authorised Representative** in South Africa.

1.2 By engaging Afrihealth, whether through our website or direct agreement, you accept these Terms in full.

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## **2. SCOPE OF SERVICES**

2.1 Afrihealth provides professional services including, but not limited to:

- Acting as Authorised Representative for foreign medical device manufacturers in South Africa;
- Assisting with SAHPRA applications and post-market regulatory compliance;
- Providing regulatory guidance and consulting in accordance with the Medicines and Related Substances Act and relevant ISO standards.

2.2 The scope of services will be agreed upon in writing for each engagement.

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## **3. CLIENT RESPONSIBILITIES**

3.1 The Client shall provide accurate, complete, and timely information and documentation as required for regulatory submissions and compliance activities.

3.2 The Client warrants that all medical devices provided for representation are legally manufactured, appropriately classified, and accompanied by necessary technical documentation.

3.3 The Client remains ultimately responsible for product safety, efficacy, and compliance with applicable laws and standards.

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## **4. FEES AND PAYMENT**

4.1 Fees for services shall be as set out in written quotations or service agreements.

4.2 All amounts are payable in South African Rand (ZAR) and exclusive of VAT unless otherwise stated.

4.3 Invoices are payable within **30 days** from date of invoice, unless otherwise agreed in writing.

4.4 Interest will accrue on overdue accounts at a rate of **2% per month**.

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## 5. CONFIDENTIALITY

5.1 Afrihealth undertakes to keep all confidential information received from the Client private and not disclose it to third parties, except where required by law or regulatory authority.

5.2 This obligation shall survive the termination of any engagement.

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## 6. INTELLECTUAL PROPERTY

6.1 All documents, reports, templates, and advice provided by Afrihealth remain its intellectual property unless otherwise agreed.

6.2 The Client may not reproduce or share such materials outside the scope of the project without prior written consent.

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## 7. LIMITATION OF LIABILITY

7.1 Afrihealth shall perform its services with reasonable care, diligence, and in accordance with applicable professional standards.

7.2 To the maximum extent permitted by South African law:

- Afrihealth shall not be liable for any indirect, special, consequential, or punitive damages (including loss of profit, business interruption, or data loss), arising out of or in connection with the services provided;
- Afrihealth's total liability to the Client for any claims, whether in contract, delict (including negligence), or otherwise, shall not exceed the total amount paid by the Client to Afrihealth for the specific services giving rise to the claim.

7.3 Afrihealth shall not be liable for:

- Errors or delays caused by inaccurate or incomplete information provided by the Client;
  - Regulatory decisions or actions made by SAHPRA or other authorities, regardless of Afrihealth's assistance or representation.
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## 8. COMPLIANCE WITH LAWS

8.1 The Client agrees to comply with all applicable South African laws and international medical device regulations.

8.2 Afrihealth shall not be liable for any non-compliance arising from the Client's failure to meet its obligations under such laws.

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## 9. TERM AND TERMINATION

9.1 Either party may terminate the engagement by giving **30 days' written notice**, unless a fixed-term agreement applies.

9.2 Termination shall not affect any accrued rights or obligations, and clauses relating to confidentiality, intellectual property, and limitation of liability shall survive termination.

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## **10. GOVERNING LAW AND DISPUTES**

10.1 These Terms and any associated engagement shall be governed by the laws of the Republic of South Africa.

10.2 Any disputes arising shall be subject to the **exclusive jurisdiction of the High Court of South Africa**, Eastern Cape Division.

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## **11. FORCE MAJEURE**

Afrihealth shall not be liable for any failure to perform due to circumstances beyond its reasonable control, including natural disasters, government action, or regulatory delays.

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## **12. AMENDMENTS**

Afrihealth reserves the right to update or amend these Terms from time to time. The latest version will be published on our website and shall apply to all new engagements.

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### **Contact Information**

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