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RESPONSE DOSSIER TO NAFDAC REVIEW OF FIELD SAFETY NOTICE (FSN)

ON

AFRIJECT 2ML AND 3ML DISPOSABLE SYRINGES

SUBMITTED TO:

National Agency for Food and Drug Administration and Control (NAFDAC)

AFRIMEDICAL MANUFACTURING AND SUPPLIES LIMITED

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Revision History

Revision	Date	Description	Author
00	10 July 2026	Initial FSCA submission	Quality Department
01	Following NAFDAC review	Updated FSN, expanded risk assessment, strengthened CAPA and recall strategy	Quality Assurance Manager

Functions	Name	Title	Sign & Date
Prepared By	Emerenini Kingsley	Quality Assurance Manager	 27-07-2026
Approved By	Gabi Alridi	General Manager	 27-07-2026

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COVER LETTER

27 July 2026

The Director

Post Marketing Surveillance Directorate

National Agency for Food and Drug Administration and Control

Lagos State.

Dear Sir/Madam,

RESPONSE TO NAFDAC REVIEW OF FIELD SAFETY NOTICE (FSN): AFRIJECT DISPOSABLE SINGLE-USE SYRINGES (2 ml & 3 ml)

Afrimedical Manufacturing and Supplies Limited acknowledges with appreciation the observations and recommendations communicated by the National Agency for Food and Drug Administration and Control (NAFDAC) regarding the Field Safety Notice (FSN) submitted for the Field Safety Corrective Action involving Afriject Disposable Single-use Syringes (2 ml and 3 ml).

We appreciate the detailed review undertaken by the Agency. The recommendations have provided valuable guidance for strengthening our Field Safety Notice and ensuring full alignment with the regulatory expectations governing medical device post-market surveillance, vigilance reporting, and Field Safety Corrective Actions.

Following receipt of your correspondence, Afrimedical immediately constituted a cross-function investigation team comprising representatives from Quality Assurance, Quality Control, Production, Engineering, Regulatory Affairs, Medical Affairs, Customer Service, Supply Chain, and Senior Management to comprehensively review the concerns raised.

A systematic review was subsequently conducted in accordance with:

NAFDAC Medical Device Regulations;

ISO 13485:2016 – Medical Devices – Quality Management Systems;

ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices;

ISO/TR 24971:2020 – Guidance on Risk Management;

WHO Medical Device Technical Series;

Good Manufacturing Practice (GMP) requirements;

Afrimedical Post-Market Surveillance, Complaint Handling, Recall and Field Safety Corrective Action procedures.

As a result of this review, Afrimedical has implemented comprehensive corrective and preventive actions aimed at strengthening product safety, regulatory compliance, customer communication, traceability, risk management, and post-market surveillance activities.

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The enclosed dossier provides a detailed response to each observation made by NAFDAC together with documentary evidence supporting the corrective actions implemented.

Afrimedical remains fully committed to patient safety, protection of healthcare professionals, continuous quality improvement, regulatory compliance, and maintaining the confidence of our customers.

We respectfully submit this response for your review and kindly request the Agency's continued guidance throughout the implementation and close-out of this Field Safety Corrective Action.

Yours faithfully,



Quality Assurance Manager

Afrimedical Manufacturing and Supplies Limited

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SECTION 1

EXECUTIVE SUMMARY

On 29 April 2026, Afrimedical Manufacturing and Supplies Limited received complaints through the post-market surveillance system regarding the withdrawal of the plunger from Afriject Disposable Single-use Syringes belonging to Batch Numbers **500224002 (2 ml)** and **500323037 (3 ml)**. The reported defect indicated that the plunger could separate from the syringe barrel during handling before or after medication administration, rendering the syringe unsuitable for its intended use. This issue was documented in the Field Safety Corrective Action Reporting Form, and internal performance testing on retained samples showed compliance with plunger pull and push force specifications, although improper handling was considered a possible contributing factor.

Following the complaints, Afrimedical initiated a Field Safety Corrective Action (FSCA), prepared a Field Safety Notice (FSN), and notified customers of the need to identify and quarantine affected batches, cease distribution, notify healthcare facilities, and arrange product return or replacement within a three-month implementation period.

After reviewing the submitted FSN, NAFDAC identified eight key areas requiring enhancement, including:

1. Inclusion of regulatory recall classification and applicable standards;
2. Expanded risk assessment with clinical consequences and severity ratings;
3. Confirmation of the scope of investigation beyond the two affected batches;
4. Additional guidance for healthcare workers where affected syringes had already been used;
5. Strengthened traceability and regulatory reporting obligations;
6. Clearer implementation timelines;
7. A comprehensive customer communication and escalation plan; and
8. clarification of replacement and compensation arrangements.

In response, Afrimedical has revised its Field Safety Notice and strengthened its Field Safety Corrective Action programme. Key improvements include:

1. Explicit reference to applicable NAFDAC medical device regulations, ISO 13485:2016, ISO 14971:2019, WHO guidance, and the proposed recall classification.
2. formal Health Hazard Evaluation linking identified hazards to potential clinical outcomes such as contamination, infection, inaccurate dosing, treatment delay, therapeutic failure, and patient harm, with documented severity and likelihood assessments.
3. Expansion of the investigation to include review of production records, complaint trends, retained samples, manufacturing controls, and distribution records for adjacent production batches to confirm whether the issue is isolated or systemic.
4. Development of comprehensive instructions for healthcare professionals, including patient monitoring, adverse event reporting, replacement of affected devices, and clinical follow-up where applicable.
5. Establishment of enhanced traceability and mandatory reporting procedures requiring distributors and healthcare facilities to notify both Afrimedical and NAFDAC of adverse events or additional complaints.
6. Introduction of defined implementation timelines: quarantine within 48 hours, customer notification within 7 days, reconciliation of distributed stock within 21 days, and completion of product return or replacement within 30 days.
7. Implementation of a structured communication plan using formal letters, e-mail, telephone calls, website notices, and direct distributor engagement, with documented escalation procedures for non-responding customers.
8. Confirmation that replacement products will be supplied at no cost to customers, with expedited delivery schedules and compensation arrangements where necessary to ensure continuity of patient care.
9. Afrimedical is committed to monitoring the effectiveness of these corrective actions through ongoing post-market surveillance, complaint trending, internal audits, management review, and periodic progress reports to NAFDAC until successful closure of the Field Safety Corrective Action.

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SECTION 2

BACKGROUND, INCIDENT INVESTIGATION AND DETAILED RESPONSE TO NAFDAC OBSERVATIONS

2.0 BACKGROUND

Afrimedical Manufacturing and Supplies Limited is a Nigerian manufacturer of sterile disposable medical devices operating under a Quality Management System designed to comply with ISO 13485:2016, applicable Good Manufacturing Practice (GMP) requirements, and the Medical Device Regulations administered by the National Agency for Food and Drug Administration and Control (NAFDAC).

Our company maintains a comprehensive Post-Market Surveillance (PMS) programme designed to monitor the safety, performance, and effectiveness of its medical devices throughout their life cycle. Inputs into the PMS programme include customer complaints, distributor feedback, healthcare facility reports, adverse event notifications, internal quality trend analysis, and regulatory intelligence.

On 29 April 2026, Afrimedical received complaints through the PMS system concerning the performance of two batches of Afriject disposable syringes, specifically Batch No. 500224002 (2 ML) and Batch No. 500323037 (3 ML). The complaints indicated that the plunger could separate from the syringe barrel during handling, rendering the device unsuitable for its intended use. These complaints triggered the company's complaint investigation process, risk evaluation, and subsequent Field Safety Corrective Action (FSCA). The initial investigation and actions are documented in the FSCA Reporting Form, while the Field Safety Notice advised customers to quarantine affected stock, stop further distribution, notify customers, and arrange return or replacement of affected devices.

2.1 CHRONOLOGY OF EVENTS

Date	Activity
29 April 2026	Complaint received through Post-Market Surveillance system
30 April 2026	Complaint investigation initiated
2 May 2026	Retention sample testing completed
5 May 2026	Cross-functional investigation commenced
8 May 2026	Preliminary risk assessment completed
10 July 2026	Initial FSCA Report submitted to NAFDAC
19 July 2026	NAFDAC review received
21 July 2026	Revision of FSN, CAPA and Risk Assessment initiated

2.2 INVESTIGATION SUMMARY

Following receipt of the complaint, Afrimedical immediately activated its Complaint Handling and Field Safety Corrective Action procedure.

A Cross-Functional investigation team comprising representatives from Quality Assurance, Quality Control, Production, Engineering, Regulatory Affairs, Supply Chain, and Customer Service conducted a comprehensive investigation. Activities included:

1. Review of Device History Records (DHRs) for the affected batches.
2. Review of Batch Manufacturing Records (BMRs).
3. Verification of Certificates of Analysis (CoAs).
4. Performance testing of retained samples, including plunger pull force and plunger push force testing.
5. Review of incoming raw material records and supplier documentation.
6. Evaluation of production environmental monitoring data.
7. Assessment of equipment calibration and preventive maintenance records.
8. Review of complaint trends for similar products and adjacent batches.

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9. Testing of retained samples demonstrated compliance with the approved product specifications and release criteria, consistent with the original batch release records.

No evidence of manufacturing nonconformity was identified during the initial investigation. Nevertheless, Afrimedical recognized that the possibility of user-related factors alone was insufficient to close the investigation. Accordingly, the scope of the investigation was expanded to include additional production batches, trend analysis, distribution records, and enhanced post-market surveillance activities to determine whether any systemic issue existed. This expanded approach addresses NAFDAC's recommendation to broaden the investigation beyond the initially affected batches.

2.3 DETAILED RESPONSE TO NAFDAC OBSERVATIONS

Observation 1: Regulatory References and Classification

NAFDAC Observation

The Field Safety Notice should clearly identify the applicable regulatory framework, recall classification, and standards governing the Field Safety Corrective Action.

Afrimedical Response

Afrimedical has revised the Field Safety Notice to include explicit references to the NAFDAC Medical Device Regulations, ISO 13485:2016 (Medical Devices – Quality Management Systems), ISO 14971:2019 (Application of Risk Management to Medical Devices), and the company's internal Recall and FSCA procedures. The revised FSN also specifies the proposed recall classification and explains the rationale for the corrective action, thereby improving transparency and regulatory alignment.

Status: Completed

Evidence: Revised Field Safety Notice (Annex A)

Observation 2: Expanded Clinical Risk Assessment

NAFDAC Observation

The Field Safety Notice should provide a more comprehensive assessment of potential clinical consequences, including the severity of harm and foreseeable patient risks.

Afrimedical Response

A formal Health Hazard Evaluation (HHE) was conducted in accordance with ISO 14971:2019. The evaluation identified the following potential clinical hazards:

1. Contamination of the sterile pathway if the plunger separates during handling.
2. Inaccurate medication dosing due to loss of syringe functionality.
3. Interruption or delay of treatment.
4. Potential therapeutic failure where a full dose is not administered.
5. Increased needle injury risk if users attempt to reassemble or replace components.
6. Requirement for repeat injection, resulting in patient discomfort and additional clinical intervention.

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Each hazard has been evaluated for severity, probability, detectability, and residual risk. The overall benefit-risk assessment supports the implementation of the FSCA while no evidence has yet been identified of a manufacturing-wide defect beyond the reported batches.

Status: Completed

Evidence: Health Hazard Evaluation Report

Observation 3: Expansion of Investigation Scope

NAFDAC Observation

The investigation should not be limited to the two reported batches but should consider whether similar issues may affect other production lots.

Afrimedical Response: Afrimedical expanded the investigation to include:

1. Review of production records for adjacent batches.
2. Review of complaint history over the preceding 24 months.
3. Additional testing of retained samples from neighbouring production lots.
4. Verification of supplier consistency for critical components.
5. Statistical review of complaint frequency.
6. Review of equipment maintenance and calibration records.
7. Verification of process capability for plunger insertion and retention operations.

At the conclusion of the expanded investigation, no evidence was identified to suggest a systemic manufacturing issue affecting additional batches. Nevertheless, enhanced post-market surveillance and complaint trending have been implemented as precautionary measures.

Status: Completed

Evidence: Investigation Report and Trend Analysis

Observation 4: Guidance for Healthcare Professionals

NAFDAC Observation

The Field Safety Notice should provide instructions for healthcare facilities where affected syringes may already have been used.

Afrimedical Response

The revised FSN now instructs healthcare providers to:

1. Immediately discontinue use of affected stock.
2. Report any suspected device malfunction to Afrimedical and NAFDAC.
3. Assess patients where incomplete medication delivery is suspected.
4. Repeat medication administration where clinically indicated using a compliant replacement syringe.

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5. Document all incidents in the institution's incident reporting system.

5. Preserve the affected device for investigation.

6. Cooperate with traceability and recall reconciliation activities.

These measures are intended to minimize patient risk while facilitating comprehensive post-market surveillance.

Status: Completed

Evidence: Revised Field Safety Notice and Healthcare Advisory

Observation 5: Traceability and reporting to NAFDAC

NAFDAC Observation

The Field Safety Notice did not include obligations to report to NAFDAC and guidance for distributors on handling stock already in circulation.

Afrimedical Response

The revised FSN now includes:

1. Notification to NAFDAC on the field safety corrective action
2. Instructions for distributors to report any serious adverse event on incidents through NAFDAC.
3. Instructions to distributors to immediately identify, quarantine, suspend further distribution and return all affected batches.
4. Guidance for the return of all affected products in line with Afrimedical and applicable regulatory recall procedure.
5. Establish communication to ensure all customers, distributors and healthcare facilities acknowledge receipt of the FSN

Status: Completed

Evidence: Revised Field Safety Notice

Observation 6: Timelines

NAFDAC Observation

The Field Safety Notice did not include timelines for quarantine, notification, return and replacement of affected product batches.

Afrimedical Response

The revised FSN notifies customers through NAFDAC to:

1. Quarantine all affected batches within 48 hours.
2. Acknowledge the receipt of field safety notice within 7 days.
3. Reconcile distributed stock within 21 days.
4. Complete product return and replacement within 30 days.

Status: Completed

Evidence: Revised Field Safety Notice, Recall communication plan.

Observation 7: Communication Plan

NAFDAC Observation

The Field Safety Notice did not include details on how customers will be notified or how escalation will be done if customers fail to respond.

Afrimedical Response

The revised FSN includes structured communication plan to customers through NAFDAC:

1. Immediate communication using formal letters, e-mail, telephone calls, website notices.
2. Follow up telephone calls for non-responding customers.

Status: Completed

Evidence: Revised Field Safety Notice, Recall communication plan, FSN Distribution record

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Observation 8: Replacement/Compensation to customers

NAFDAC Observation

The Field Safety Notice did not include details and timelines for the replacement of affected products to customers.

Afrimedical Response

The revised FSN includes detailed replacement/compensation plan to customers through NAFDAC:

1. Replacement product shall be dispatched within 14 days following verification and receipt of affected stock.
2. Where immediate replacement stock is unavailable, Customers will be informed of the expected delivery date and Priority allocation.
3. Where replacement is not feasible, appropriate compensation will be implemented in accordance with commercial and any applicable regulatory agreement.

Status: Completed

Evidence: Revised Field Safety Notice, Replacement and Distribution record.

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SECTION 3

ROOT CAUSE ANALYSIS, HEALTH HAZARD EVALUATION (HHE), AND RISK MANAGEMENT REPORT

3.0 PURPOSE

This section presents the comprehensive technical evaluation conducted following the receipt of complaints associated with Afriject Disposable Single-use Syringes (2 mL and 3 mL). The purpose of the investigation was to determine the root cause of the reported plunger withdrawal, evaluate the potential health hazards associated with the defect, assess patient risk in accordance with ISO 14971:2019, and establish appropriate risk control measures supporting the Field Safety Corrective Action (FSCA).

The investigation was conducted in accordance with:

1. ISO 13485:2016 – Medical Devices – Quality Management Systems.
2. ISO 14971:2019 – Application of Risk Management to Medical Devices.
3. ISO/TR 24971:2020 – Guidance on the application of ISO 14971.
4. NAFDAC Medical Device Regulations.
5. Afrimedical Complaint Handling, CAPA, Risk Management, and Recall Procedures.

3.1 INVESTIGATION OBJECTIVES

The investigation was designed to:

1. Confirm the validity of the reported complaint.
2. Determine whether the issue originated from manufacturing, materials, equipment, packaging, transportation, storage, or use.
3. Evaluate whether the defect was isolated or systemic.
4. Assess potential patient and user hazards.
5. Establish appropriate corrective and preventive actions.
6. Demonstrate compliance with regulatory expectations and quality system requirements.

3.2 INVESTIGATION TEAM

Department	Responsibility
Quality Assurance	Investigation Lead, Clinical Risk Evaluation
Regulatory Affairs	Regulatory Compliance Review
Quality Control	Laboratory Testing
Production	Manufacturing Record Review
Engineering	Equipment Assessment
Supply Chain	Raw Material Traceability, Distribution Reconciliation
Top Management	Management Review and Approval

3.3 INVESTIGATION ACTIVITIES

The following activities were completed as part of the technical investigation:

1. Review of customer complaints.

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2. Review of complaint trending over the previous twenty-four (24) months.
3. Review of Device History Records (DHRs).
4. Review of Batch Manufacturing Records (BMRs).
5. Verification of sterilization records
6. Verification of production environmental monitoring results.
7. Review of equipment qualification and calibration records.
8. Review of preventive maintenance records.
9. Examination of retained samples.
10. Plunger pull force testing.
11. Plunger push force testing.
12. Visual inspection of syringe components.
13. Supplier performance review.
14. Review of incoming inspection records.
15. Review of process validation reports.
16. Expansion of investigation to adjacent production batches.
17. Review of customer distribution records.

3.4 ROOT CAUSE ANALYSIS

3.4.1 Problem Statement

Customers reported that the plunger could be unintentionally withdrawn completely from the syringe barrel during handling before or during intended use, resulting in loss of device functionality and rendering the syringe unsuitable for safe administration of medication.

3.4.2 Five-Why Analysis

Question	Finding
Why did the plunger withdraw from the barrel?	The plunger disengaged from the barrel before or during intended use.
Why could the plunger disengage?	In isolated field reports, resistance between the stopper and barrel was insufficient to prevent withdrawal under certain handling conditions.
Why was resistance insufficient?	No manufacturing deviation was identified in retained samples; however, user handling, transportation stresses, and component interaction required further assessment.
Why was this not detected before market release?	Routine release testing demonstrated compliance with established specifications; the reported field condition was not reproduced during routine quality control testing.
Why should additional action be taken?	Although manufacturing records were compliant, the occurrence of field complaints warranted enhanced risk assessment, broader trend analysis, and strengthened post-market surveillance to ensure continued patient safety.

Conclusion

The investigation did not identify a confirmed manufacturing defect. The event is considered multi-factorial pending continued monitoring. Nevertheless, the occurrence justified implementation of precautionary Field Safety Corrective Actions.

3.4.3 Fishbone (Ishikawa) Analysis

Materials

1. Review of plunger specification.
2. Review of barrel dimensional conformity.

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3. Supplier Certificates of Analysis verified.

4. No material nonconformities identified.

Machine

1. Moulding equipment reviewed.
2. Assembly equipment reviewed.
3. Preventive maintenance current.
4. Calibration status verified.

Methods

1. Manufacturing procedures followed.
2. Process validation reviewed.

No deviations identified.

Manpower

1. Training records reviewed.
2. Operator competency confirmed.

No evidence of operator error.

Measurement

1. QC release testing within specification.
2. Measuring equipment calibrated.

Laboratory records verified.

Environment

1. Cleanroom environmental monitoring acceptable.
2. Temperature and humidity records compliant.
3. Differential pressure records satisfactory.

3.5 ROOT CAUSE CONCLUSION

The investigation did not identify evidence of a systemic manufacturing or quality control failure. However, because complaints were received from the field, Afrimedical elected to implement precautionary Field Safety Corrective Actions, strengthen complaint trending, enhance user communication, and expand surveillance activities in accordance with the precautionary principle and regulatory expectations.

3.6 HEALTH HAZARD EVALUATION (HHE)

Objective

To evaluate the potential health impact associated with unintended plunger withdrawal during the use of the affected syringes.

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Hazard Identification

Potential hazards include:

1. Interruption of medication administration.
2. Under-dosing or incomplete drug delivery.
3. Delay in treatment.
4. Requirement for repeat injection.
5. Loss of sterility if the device is manipulated after plunger separation.
6. Increased risk of contamination.
7. Psychological distress to patient.
8. Potential needlestick injury to healthcare personnel during replacement procedures.

Clinical Consequences

Possible clinical outcomes include:

Low Severity

1. Minor treatment delay.
2. Additional patient discomfort.
3. Replacement of syringe.

Moderate Severity

1. Delayed therapeutic effect.
2. Incomplete medication administration.
3. Additional clinical intervention.

High Severity (Rare)

Where critical medications are involved:

1. Delay in emergency treatment.
2. Potential deterioration of patient condition.
3. Reduced therapeutic effectiveness.

No confirmed patient injuries attributable to the reported issue had been identified during the investigation period.

3.7 SEVERITY CLASSIFICATION

Severity	Description
Negligible	No injury
Minor	Temporary inconvenience
Moderate	Temporary medical intervention required
Serious	Serious deterioration of health
Critical	Life-threatening consequences
Catastrophic	Death

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The reported defect was assessed as **Moderate to Serious**, depending on the clinical application of the syringe and the medication being administered.

3.8 PROBABILITY ASSESSMENT

Likelihood	Description
Remote	Extremely unlikely
Low	Isolated complaints
Medium	Occasional occurrence
High	Repeated occurrence
Very High	Frequent occurrence

Based on complaint frequency and distribution data, the probability was assessed as **Low**.

3.9 RISK EVALUATION MATRIX

Severity	Probability	Initial Risk
Moderate	Low	Medium
Serious	Low	High

The overall risk profile supported implementation of a Field Safety Corrective Action as a precautionary measure.

3.10 RISK CONTROL MEASURES

The following controls have been implemented:

1. Immediate Field Safety Notice issued.
2. Product quarantine initiated.
3. Distribution suspended for affected batches.
4. Customer notification programme implemented.
5. Product replacement programme initiated.
6. Expanded investigation completed.
7. Enhanced complaint monitoring implemented.
8. Additional post-market surveillance initiated.
9. Internal training conducted for Quality, Production, and Customer Service personnel.
10. Management Review convened to evaluate effectiveness.

3.11 RESIDUAL RISK EVALUATION

Following implementation of the above controls:

Risk	Initial	Residual
Incomplete medication delivery	High	Low
Contamination	Medium	Low
Treatment delay	Medium	Low
Repeat injection	Medium	Low

Residual risks were considered acceptable when weighed against the benefits of continued availability of compliant replacement products and the implementation of comprehensive corrective actions.

3.12 BENEFIT-RISK ANALYSIS

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Afrimedical concluded that:

1. The identified risk is limited to specific affected batches under Field Safety Corrective Action.
2. No evidence indicates a systemic manufacturing failure.
3. Comprehensive corrective measures significantly reduce residual risk.
4. Continued distribution of unaffected products remains justified.
5. The benefits of replacing affected products and maintaining uninterrupted patient access to compliant syringes outweigh the residual risks identified.

3.13 MANAGEMENT REVIEW OF INVESTIGATION

1. Top Management reviewed the findings of the investigation and approved the following actions:
2. Implementation of all corrective and preventive actions.
3. Revision of the Field Safety Notice.
4. Expansion of customer communication activities.
5. Submission of this enhanced regulatory dossier to NAFDAC.
6. Monthly review of complaint trends for the next twelve (12) months.
7. Quarterly effectiveness review through the Management Review process.
8. Annual reassessment of the Risk Management File in accordance with ISO 14971.

3.14 CONCLUSION

Afrimedical Manufacturing and Supplies Limited concludes that the investigation has been conducted in a systematic, scientifically justified, and risk-based manner consistent with ISO 13485:2016 and ISO 14971:2019. Although no definitive systemic manufacturing defect was confirmed, we implemented extensive Field Safety Corrective Actions to ensure continued protection of patients, healthcare professionals, and end users.

The findings presented in this section support the continued implementation of the FSCA, the enhanced post-market surveillance programme, and the comprehensive CAPA activities detailed in the subsequent Section.

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SECTION 4
CORRECTIVE AND PREVENTIVE ACTION (CAPA) PROGRAMME
Comprehensive Response to NAFDAC Review of the Field Safety Notice (FSN)
4.0 PURPOSE

This section documents the comprehensive Corrective and Preventive Action (CAPA) programme initiated by Afrimedical Manufacturing and Supplies Limited following the Field Safety Corrective Action (FSCA) involving Afriject Disposable Single-use Syringes (2 mL and 3 mL).

The CAPA programme was developed in accordance with:

1. ISO 13485:2016 – Clause 8 (Measurement, Analysis and Improvement)
2. ISO 14971:2019 – Risk Control Measures
3. NAFDAC Medical Device Regulations
4. Afrimedical CAPA Procedure
5. Complaint Handling Procedure
6. Recall and Field Safety Corrective Action Procedure
7. Deviation and CAPA Procedure

The objective of the CAPA programme is to eliminate the immediate issue, prevent recurrence, strengthen the Quality Management System (QMS), and demonstrate sustained compliance with regulatory requirements.

4.1 CAPA OBJECTIVES

The CAPA programme aims to:

1. Address the observations raised by NAFDAC.
2. Investigate and eliminate potential causes of the reported defect.
3. Improve product safety and reliability.
4. Strengthen complaint handling and post-market surveillance.
5. Enhance product traceability and recall effectiveness.
6. Improve communication with distributors, healthcare facilities, and regulatory authorities.
7. Verify the effectiveness of implemented actions through measurable quality indicators.

4.2 CAPA GOVERNANCE

A Cross-functional CAPA Review Committee was established to oversee implementation.

Function	Responsibility
Managing Director	Executive Oversight, Clinical Risk Review
Quality Assurance Manager	CAPA Owner
Regulatory Affairs Manager	Regulatory Compliance
Production Manager	Manufacturing Controls
Quality Control Manager	Product Testing
Engineering Manager	Equipment & Validation
Supply Chain coordinator	Supplier Controls
Marketing Manager	Complaint & Recall Coordination

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The committee meets weekly during the implementation phase and monthly thereafter until CAPA closure.

4.3 IMMEDIATE CORRECTION ACTIONS

The following immediate actions were implemented immediately after confirmation of the field complaints:

Action	Status	Completion
Activation of Complaint Investigation Procedure	Completed	Immediate
Activation of Field Safety Corrective Action (FSCA)	Completed	Immediate
Issue of Field Safety Notice (FSN)	Completed	Immediate
Suspension of distribution of affected batches	Completed	Within 24 hours
Quarantine of warehouse stock	Completed	Within 24 hours
Notification of distributors	Completed	Within 48 hours
Notification of healthcare facilities	Completed	Within 72 hours
Establishment of Recall Coordination Team	Completed	Within 24 hours

4.4 DETAILED CAPA PLAN

CAPA No.	Observation	Root Cause	Corrective Action	Preventive Action	Responsibility	Target Date	Status
CAPA-001	FSN lacked sufficient regulatory references	FSN template did not require detailed regulatory citations	Revise FSN to include NAFDAC regulations, ISO 13485 and ISO 14971 references	Update FSN SOP and approval checklist	QA / Regulatory Affairs	7 days	Closed
CAPA-002	Clinical risk assessment not sufficiently detailed	Initial HHE focused on product performance rather than patient impact	Conduct comprehensive Health Hazard Evaluation	Revise Risk Management Procedure to require clinical risk assessment	QA / Medical Affairs	14 days	Closed
CAPA-003	Investigation limited to reported batches	Investigation scope defined by initial complaint	Expand review to adjacent production lots and complaint trends	Revise Complaint Investigation SOP to require broader trend analysis	QA / Production	21 days	Closed
CAPA-004	Inadequate guidance to healthcare providers	FSN did not include post-use clinical guidance	Issue revised Healthcare Advisory	Include standard clinical guidance template in all future FSNs	Regulatory Affairs	14 days	Closed
CAPA-005	Communication plan required enhancement	Existing recall communication matrix insufficient	Develop structured communication and escalation plan	Annual validation of recall communication process	Marketing	14 days	Closed
CAPA-	Product	Replacement	Develop	Integrate into	Supply Chain	21 days	Closed

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006	replacement process not fully described	logistics not documented	replacement and reconciliation procedure	Recall SOP			
CAPA-007	Timelines not clearly defined	Existing FSN template lacked implementation milestones	Include mandatory implementation timelines	SOP revision	QA	7 days	Closed
CAPA-008	Traceability and regulatory reporting required strengthening	Reporting responsibilities not sufficiently defined	Revise traceability and vigilance procedures	Quarterly traceability drills	QA / Regulatory Affairs	30 days	Open (Monitoring)

4.5 QUALITY MANAGEMENT SYSTEM IMPROVEMENTS

Afrimedical has undertaken the following QMS enhancements:

4.5.1 Complaint Handling Procedure

The Complaint Handling SOP has been revised to require:

1. Mandatory risk categorization of all complaints.
2. Immediate escalation of potential patient safety issues.
3. Trend analysis after every five similar complaints or quarterly, whichever occurs first.
4. Integration with CAPA and Risk Management processes.

4.5.2 Field Safety Corrective Action Procedure

The FSCA SOP has been updated to include:

1. Mandatory Health Hazard Evaluation.
2. Defined regulatory notification timelines.
3. Standardized FSN templates.
4. Effectiveness check methodology.
5. Product reconciliation requirements.
6. Final FSCA close-out reporting.

4.5.3 Recall Procedure

The Recall SOP now includes:

1. Recall classification criteria.
2. Customer communication matrix.
3. Distribution reconciliation process.
4. Product disposition requirements.
5. Recall effectiveness checks.
6. Lessons learned review.

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4.6 TRAINING PROGRAMME

Following the CAPA implementation, targeted training was conducted for relevant personnel.

Department	Training Topic	Frequency
Quality Assurance	CAPA & Risk Management	Annual
Regulatory Affairs	FSCA and NAFDAC Reporting	Annual
Production	Complaint Escalation	Annual
Quality Control	Investigation Documentation	Annual
Marketing	Recall Communication	Annual
Warehouse	Product Quarantine & Traceability	Annual
Supply Chain	Distribution Reconciliation	Annual

Training records, attendance sheets, competency assessments, and effectiveness evaluations are maintained as objective evidence.

4.7 EFFECTIVENESS VERIFICATION PLAN

Afrimedical will verify the effectiveness of the CAPA programme using the following Key Performance Indicators (KPIs):

KPI	Target	Monitoring Frequency
Similar complaints	Zero recurrence attributable to the same cause	Monthly
Complaint investigation closure	≤30 calendar days	Monthly
Recall response rate	≥95% customer acknowledgement	Weekly during FSCA
Product reconciliation	≥98% accounted-for distributed units	Weekly
CAPA implementation	100% completed within agreed timelines	Monthly
Internal audit findings	No major findings related to FSCA	Quarterly

Where performance falls below target, additional corrective actions will be initiated.

4.8 INTERNAL AUDIT PROGRAMME

A focused internal audit programme has been scheduled to verify implementation of the corrective actions.

The audit scope includes:

1. Complaint Handling.
2. CAPA implementation.
3. Recall management.
4. Product traceability.
5. Risk management.
6. Regulatory reporting.
7. Distribution controls.
8. Document control.

Audit findings will be reviewed during Management Review meetings, and any nonconformities will be addressed through additional CAPA activities.

4.9 MANAGEMENT REVIEW

Top Management has committed to monitoring the CAPA programme through formal Management Review meetings.

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Agenda items include:

1. Review of complaint trends.
2. Progress of recall activities.
3. CAPA implementation status.
4. Customer feedback.
5. Regulatory correspondence.
6. Internal audit findings.
7. Effectiveness of corrective actions.
8. Resource requirements.

Minutes of each Management Review meeting will be retained as objective evidence and made available to NAFDAC upon request.

4.10 REGULATORY COMMITMENTS

Afrimedical commits to:

1. Submit periodic progress updates to NAFDAC until closure of the FSCA.
2. Notify NAFDAC immediately of any new adverse events related to the affected products.
3. Continue enhanced post-market surveillance for at least twelve (12) months.
4. Maintain complete traceability records for all affected batches.
5. Conduct quarterly reviews of complaint trends.
6. Reassess the Risk Management File annually or sooner if additional information becomes available.
7. Ensure all revised procedures remain effective through routine internal audits and Management Reviews.

4.11 CAPA EFFECTIVENESS REVIEW

The CAPA programme will be considered effective when:

1. All corrective and preventive actions have been implemented.
2. Verification activities confirm sustained compliance.
3. No recurrence of the reported issue is observed over a defined monitoring period.
4. Recall reconciliation and customer communication objectives have been achieved.
5. NAFDAC accepts the submitted evidence and formally closes the regulatory observations.

4.12 CONCLUSION

Afrimedical Manufacturing and Supplies Limited has implemented a structured and risk-based CAPA programme designed to address the observations raised by NAFDAC, strengthen the Quality Management System, and reinforce patient safety.

The actions described in this section demonstrate the organization's commitment to continual improvement, regulatory compliance, and the effective management of post-market issues. Ongoing monitoring, internal audits, management oversight, and enhanced post-market surveillance will ensure that the implemented actions remain effective and that any emerging risks are promptly identified and addressed.

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SECTION 5

FIELD SAFETY CORRECTIVE ACTION (FSCA) IMPLEMENTATION, RECALL STRATEGY, DISTRIBUTION TRACEABILITY, CUSTOMER COMMUNICATION PLAN, AND EFFECTIVENESS VERIFICATION

Response to NAFDAC Review of the Field Safety Notice (FSN)

5.0 PURPOSE

This section documents the comprehensive implementation strategy adopted by Afrimedical Manufacturing and Supplies Limited for the execution of the Field Safety Corrective Action (FSCA), product recall, traceability activities, customer communication programme, product reconciliation, effectiveness verification, and regulatory reporting.

The procedures described herein have been developed to ensure full compliance with:

1. NAFDAC Medical Device Regulations.
2. ISO 13485:2016 (Clauses 7.5.8, 8.2.1, 8.2.2, 8.3, 8.5.2 and 8.5.3).
3. ISO 14971:2019.
4. WHO Guidance on Medical Device Recalls.
5. Afrimedical Recall, Complaint Handling, and Field Safety Corrective Action Procedures.

5.1 OBJECTIVES OF THE FIELD SAFETY CORRECTIVE ACTION

The objectives of the FSCA are to:

1. Protect patients and healthcare professionals from potential risks associated with the affected syringes.
2. Prevent further distribution and use of the affected batches.
3. Ensure rapid identification and retrieval of affected products.
4. Maintain uninterrupted supply of compliant replacement products.
5. Ensure transparent communication with all stakeholders.
6. Demonstrate compliance with regulatory requirements.
7. Verify the effectiveness of the recall process.
8. Prevent recurrence through continual improvement.

5.2 FSCA GOVERNANCE STRUCTURE

A dedicated **Field Safety Corrective Action Management Team** was established to oversee implementation.

Position	Responsibility
General Manager	Executive Sponsor
Quality Assurance Manager	FSCA Coordinator
Regulatory Affairs Manager	NAFDAC Liaison
Production Manager	Product Control
Supply Chain Coordinator	Logistics & Distribution, Quarantine & Reconciliation
Marketing Manager	Customer Communication
Medical Affairs Representative	Clinical Support

The FSCA Coordinator reports directly to Executive Management throughout the implementation period.

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5.3 RECALL CLASSIFICATION

Based on the available evidence, Afrimedical classified the action as a **Class II recall** implemented through a **precautionary Field Safety Corrective Action** involving specific production batches of Afriject Disposable Single-use Syringes. The decision was informed by the potential for plunger withdrawal to affect device functionality and patient care, while the investigation did not identify evidence of a systemic manufacturing defect.

The classification will remain under review should additional information emerge through complaint investigations or post-market surveillance.

5.4 AFFECTED PRODUCTS

Product	Batch Number	Manufacturing Date	Expiry Date	Status
Afriject Disposable Syringe 2 mL	500224002	Refer to Batch Record	Refer to Label	Subject to FSCA
Afriject Disposable Syringe 3 mL	500323037	Refer to Batch Record	Refer to Label	Subject to FSCA

The affected batches have been identified through the company's product traceability system, enabling rapid communication and reconciliation.

5.5 PRODUCT TRACEABILITY

Afrimedical maintains complete traceability from raw material receipt to customer distribution. For the affected batches, the following records were reviewed:

1. Raw material batch records.
2. Incoming inspection records.
3. Production batch records.
4. Sterilization records.
5. Final release documentation.
6. Warehouse inventory.
7. Distribution records.
8. Customer shipment records.
9. Complaint records.

This traceability enabled the preparation of a comprehensive distribution list for all affected customers and facilitated targeted recall activities.

5.6 DISTRIBUTION RECONCILIATION

A reconciliation exercise was initiated immediately following the FSCA.

Distribution Stage	Verification Activity
Manufacturing	Confirm quantities produced
Finished Goods Warehouse	Verify inventory on hand
Distributor	Confirm quantities received
Healthcare Facilities	Confirm quantities supplied
Retail Customers	Confirm remaining stock
Returned Product	Verify quantities recovered
Replacement Product	Confirm quantities reissued

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Reconciliation records are maintained electronically and reviewed weekly until closure of the FSCA.

5.7 CUSTOMER COMMUNICATION PLAN

A structured communication plan was implemented to ensure all stakeholders received timely, accurate, and consistent information.

Primary Communication Channels

Formal notification letters, Electronic mail, Telephone calls, Distributor meetings, Website notification (where appropriate), Direct engagement with healthcare facilities and Regulatory notifications.

Information Included in Communications

Description of the affected products, Batch identification, Nature of the issue, Potential risks., Immediate actions required, Product quarantine instruction, Return and replacement procedure, Contact information for Afrimedical, Instructions for reporting adverse events to Afrimedical and NAFDAC.

5.8 ESCALATION PROCEDURE

Where customers did not acknowledge receipt of the FSN within five (5) working days, the following escalation process was implemented:

Day	Action
Day 1	Email notification
Day 3	Telephone follow-up
Day 5	Second written reminder
Day 7	Escalation to Distributor
Day 10	Site visit (where required)
Day 14	Final escalation to Executive Management

All communication attempts are documented within the Recall Communication Log.

5.9 PRODUCT QUARANTINE

Upon notification, customers were instructed to:

Identify affected batches, Immediately cease use, Segregate stock, Clearly label products as "Quarantined – Do Not Use.", Prevent further distribution, Await collection instructions from Afrimedical and Returned products are stored in a designated quarantine area pending investigation and final disposition.

5.10 PRODUCT RETURN PROCESS

The return process includes:

Customer notification of available quantities, Verification against shipment records, Issuance of Return Authorization, Collection by approved logistics providers, Receipt verification, Inspection upon arrival, Reconciliation against distribution records, Secure storage and Final disposition in accordance with approved procedures

5.11 PRODUCT REPLACEMENT PROGRAMME

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To minimize disruption to healthcare services, Afrimedical implemented a replacement programme.

Customers returning affected products receive:

Replacement syringes meeting current release specifications, Replacement at no cost, Priority shipment, Technical support where required, Confirmation of replacement quantities, Where replacement is not immediately available, interim arrangements are made to ensure continuity of patient care.

5.12 EFFECTIVENESS CHECKS

Effectiveness checks are conducted to verify the success of the FSCA.

Performance Indicators

Indicator	Target
Customer acknowledgement	≥95%
Product reconciliation	≥98%
Product recovery	≥95%
Communication completion	100%
Replacement completion	100%
New complaints related to affected batches	Zero following completion

Independent verification is performed by the Internal Audit function.

5.13 POST-MARKET SURVEILLANCE ENHANCEMENTS

Afrimedical has strengthened its Post-Market Surveillance programme by:

1. Increasing complaint trend analysis frequency from quarterly to monthly.
2. Expanding market feedback collection from distributors and healthcare facilities.
3. Conducting targeted surveillance of replacement batches.
4. Monitoring field performance through customer follow-up.
5. Reviewing adverse event reports in real time.

Findings are reported to the CAPA Committee and Management Review.

5.14 REGULATORY REPORTING

Afrimedical commits to maintaining open communication with NAFDAC throughout the FSCA.

The following reports will be submitted:

Report	Timeline
Initial FSCA Report	Submitted
Progress Report 1	30 days
Progress Report 2	60 days
Progress Report 3	90 days
Final Effectiveness Report	Upon completion
FSCA Close-Out Report	After regulatory acceptance

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Any significant new findings or adverse events will be reported immediately.

5.15 MANAGEMENT REVIEW OF FSCA

Top Management reviews the FSCA monthly during implementation. Review topics include:

Recall progress, Customer responses, Product reconciliation, Complaint trend, CAPA implementation, Regulatory correspondence, Resource allocation, Effectiveness of corrective actions, and Actions arising from Management Review are tracked to completion.

5.16 LESSONS LEARNED

Following completion of the FSCA, Afrimedical will conduct a formal lessons-learned exercise to:

Evaluate the effectiveness of the recall, Identify opportunities for process improvement, Strengthen the Quality Management System, Enhance future Field Safety Notices, Improve communication with regulators and customers, Refine risk management and post-market surveillance activities, Recommendations will be incorporated into revised procedures and future training programme

5.17 CONCLUSION

The Field Safety Corrective Action described in this section demonstrates Afrimedical Manufacturing and Supplies Limited's commitment to protecting patients, supporting healthcare providers, and maintaining full regulatory compliance. Through comprehensive traceability, structured communication, effective product reconciliation, robust replacement arrangements, and ongoing post-market surveillance, Afrimedical has implemented a systematic and risk-based response consistent with ISO 13485:2016, ISO 14971:2019, and NAFDAC regulatory expectations.

The effectiveness of the FSCA will continue to be monitored through defined performance indicators, internal audits, management review, and regular reporting to NAFDAC until formal closure of the action.

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SECTION 6

REVISED FIELD SAFETY NOTICE (FSN), FIELD SAFETY CORRECTIVE ACTION (FSCA) IMPLEMENTATION PLAN, AND HEALTHCARE PROFESSIONAL ADVISORY

Response to NAFDAC Review of the Field Safety Notice

6.0 PURPOSE

This section provides the revised Field Safety Notice (FSN) prepared in response to the observations made by the National Agency for Food and Drug Administration and Control (NAFDAC). The revised FSN incorporates the Agency's recommendations by strengthening the regulatory references, expanding the risk assessment, providing additional guidance to healthcare professionals, defining implementation timelines, and clarifying traceability, reporting, and communication requirements.

This document forms part of Afrimedical Manufacturing and Supplies Limited's comprehensive Field Safety Corrective Action (FSCA) programme and shall be distributed to all affected distributors, healthcare institutions, procurement agencies, and other stakeholders.

6.1 SCOPE

This FSN applies to the following products:

Product Description	Batch Number	Device Status
Afriject Disposable Syringe – 2 ML	500224002	Subject to FSCA
Afriject Disposable Syringe – 3 ML	500323037	Subject to FSCA

The notice applies to:

Distributors, Importers, Wholesalers, Hospitals, Clinics, Pharmacies, Government Procurement Agencies, Healthcare Professionals and End Users,

6.2 REGULATORY REFERENCES

This Field Safety Notice has been prepared in accordance with:

1. NAFDAC Medical Device Regulations.
2. ISO 13485:2016 – Medical Devices – Quality Management Systems.
3. ISO 14971:2019 – Application of Risk Management to Medical Devices.
4. ISO/TR 24971:2020 – Guidance on Risk Management.
5. WHO Guidance on Medical Device Vigilance and Recall.
6. Afrimedical Recall Procedure.
7. Afrimedical Complaint Handling Procedure.
8. Afrimedical Field Safety Corrective Action Procedure.

6.3 REVISED FIELD SAFETY NOTICE (FSN)

SUBJECT

Urgent Field Safety Notice (FSN): Afriject Disposable Single-use Syringes (2 mL and 3 mL)

Dear Valued Customer,

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Afrimedical Manufacturing and Supplies Limited is issuing this Field Safety Notice as part of a voluntary Field Safety Corrective Action (FSCA) concerning specific batches of Afriject Disposable Single-use Syringes.

This action is being undertaken following reports that, under certain circumstances, the syringe plunger may separate completely from the barrel during handling or use, resulting in loss of device functionality.

Although the investigation has not identified evidence of a systemic manufacturing defect, Afrimedical has elected to implement this precautionary FSCA in the interest of patient safety and regulatory compliance.

Affected Products

Product	Batch Number
Afriject Disposable Syringe – 2 mL	500224002
Afriject Disposable Syringe – 3 mL	500323037

No other batches are currently included in this Field Safety Corrective Action.

6.4 DESCRIPTION OF THE ISSUE

Afrimedical has received complaints indicating that the syringe plunger may unintentionally disengage from the syringe barrel before or during intended clinical use.

Potential consequences include:

Inability to administer medication, Incomplete medication delivery, Delay in treatment, Requirement to repeat the injection, Increased handling of sterile components, Potential contamination if aseptic technique is compromised, Potential patient discomfort and inconvenience.

At the time of this notice, Afrimedical has not confirmed any serious patient injury directly attributable to the reported issue.

6.5 HEALTH HAZARD EVALUATION SUMMARY

A formal Health Hazard Evaluation was conducted in accordance with ISO 14971:2019.

Potential risks include:

Hazard	Potential Consequence	Residual Risk
Plunger separation	Incomplete dose administration	Low
Treatment interruption	Delay in therapy	Low
Loss of sterility	Infection risk	Low
Repeat injection	Patient discomfort	Low
Additional handling	Needlestick injury	Low

Following implementation of the FSCA, the overall residual risk has been assessed as acceptable.

6.6 ACTIONS REQUIRED BY DISTRIBUTORS

Distributors are required to:

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Immediately identify affected stock, Stop further distribution, Quarantine affected products, Inform all downstream customers, Complete product reconciliation, Return affected stock to Afrimedical and Confirm completion of all recall activities within the specified timeline

6.7 ACTIONS REQUIRED BY HEALTHCARE FACILITIES

Healthcare institutions must:

Immediately stop using affected batches, Segregate affected products, Label products "Do Not Use.", Notify relevant clinical departments, Arrange return through the distributor or Afrimedical, Report any device malfunction or adverse event to Afrimedical and NAFDAC, Maintain records of returned quantities,

6.8 GUIDANCE FOR HEALTHCARE PROFESSIONALS

Where an affected syringe has already been used:

Healthcare professionals should:

1. Assess whether the full intended dose of medication was administered.
2. Monitor the patient where incomplete medication delivery is suspected.
3. Repeat treatment where clinically justified.
4. Document the incident in accordance with institutional procedures.
5. Preserve the device for investigation.
6. Notify Afrimedical immediately.
7. Submit adverse event reports to NAFDAC where appropriate.

No additional treatment is required solely because a patient was exposed to a syringe from the affected batches if no malfunction occurred during use.

6.9 PRODUCT REPLACEMENT

Afrimedical will replace all returned affected syringes at no cost.

Replacement products:

Have undergone routine quality release testing, comply with approved specifications, are manufactured under validated processes, are fully traceable,

Replacement shipments will be prioritised to minimise disruption of healthcare services.

6.10 TRACEABILITY REQUIREMENTS

Customers are requested to provide:

Product description, Batch number, Quantity received, Quantity used, Quantity remaining, Quantity returned and Date of return,

These records will support complete reconciliation and regulatory reporting.

6.11 IMPLEMENTATION TIMELINE

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Activity	Timeline
Issue FSN	Day 0
Customer acknowledgement	Within 5 working days
Product quarantine	Within 48 hours
Product reconciliation	Within 21 days
Product return	Within 30 days
Product replacement	Within 30 days
Final effectiveness verification	Within 90 days

6.12 CUSTOMER ACKNOWLEDGEMENT

Customers are requested to complete an acknowledgement confirming:

Receipt of this Field Safety Notice, Identification of affected products, Completion of product quarantine, Notification of all relevant users, Return of affected products and Acknowledgements will be retained as objective evidence of recall effectiveness.

6.13 COMMUNICATION PLAN

Afrimedical will communicate with stakeholders through:

Formal notification letters, Electronic mail, Telephone follow-up, Distributor meetings, Healthcare facility visits where required, Regulatory reporting and Company website (where appropriate),

Escalation procedures will be initiated for customers who fail to acknowledge receipt or complete required actions within the specified timeframe.

6.14 MONITORING OF FSCA EFFECTIVENESS

The effectiveness of this Field Safety Corrective Action will be assessed using the following indicators:

Indicator	Target
Customer acknowledgement	≥95%
Product reconciliation	≥98%
Product recovery	≥95%
Product replacement	100%
Repeat complaints	Zero confirmed recurrence attributable to the same cause

Performance will be reviewed weekly by the FSCA Management Team and reported to Senior Management and NAFDAC.

6.15 REGULATORY REPORTING

Afrimedical will submit the following reports to NAFDAC:

1. Initial FSCA notification (submitted).
2. Thirty-day progress report.
3. Sixty-day progress report.
4. Ninety-day effectiveness report.
5. Final FSCA close-out report.
6. Immediate notification of any significant new adverse events or emerging risks.

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6.16 DECLARATION OF COMMITMENT

Afrimedical Manufacturing and Supplies Limited remains committed to protecting patients, healthcare professionals, distributors, and end users by maintaining the highest standards of product quality, regulatory compliance, and post-market vigilance.

We acknowledge the observations made by NAFDAC and has incorporated the Agency's recommendations into this revised Field Safety Notice and the broader Field Safety Corrective Action programme. Continuous monitoring, complaint trending, risk management, and management review activities will ensure that the implemented corrective and preventive actions remain effective.

6.17 CONCLUSION

This revised Field Safety Notice addresses the regulatory gaps identified during NAFDAC's review by providing enhanced clinical guidance, expanded risk communication, clear implementation timelines, strengthened traceability requirements, and robust customer communication processes.

The revised FSN, together with the associated CAPA programme, Health Hazard Evaluation, Risk Management Report, and Recall Strategy contained in the preceding Section, demonstrates Afrimedical's commitment to transparency, continual improvement, and full regulatory compliance.

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SECTION 7

RISK MANAGEMENT REVIEW AND BENEFIT-RISK ASSESSMENT

7.1 OBJECTIVE

The purpose of this review is to evaluate the impact of the identified nonconformity on the safety, quality and performance of the affected medical devices and to determine whether the overall benefit-risk profile remains acceptable following implementation of the Field Safety Corrective Action (FSCA).

7.2 RISK MANAGEMENT PROCESS

Afrimedical Manufacturing and Supplies Limited maintains a documented Risk Management System in accordance with:

1. ISO 14971:2019 – Medical devices – Application of risk management to medical devices
2. ISO 13485:2016
3. Company's Risk Management Procedure
4. The investigation team reconvened the Risk Management Committee to reassess all identified hazards associated with the reported issue.

The review included:

Complaint trend analysis, Production records, Batch Manufacturing Records (BMR), Finished product testing records, Process validation reports, Device History Records, Distribution records, Customer complaints, Post-market surveillance data and CAPA investigation findings

7.3 HAZARD IDENTIFICATION

The following hazards were reviewed.

Hazard	Possible Harm	Severity	Probability Before FSCA	Probability After FSCA
Product dimensional variation	Poor clinical performance	Medium	Low	Very Low
Sterility compromise	Infection	High	Remote	Negligible
Leakage	Medication loss	Medium	Low	Very Low
Needle disengagement	Delay in treatment	Medium	Remote	Negligible
Device malfunction	Repeat injection	Medium	Low	Very Low
User dissatisfaction	Treatment delay	Low	Medium	Low

7.4 ROOT CAUSE ASSESSMENT

The multidisciplinary investigation concluded that the issue originated from process variability during manufacturing rather than from design deficiencies.

No evidence was found indicating:

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design failure, material incompatibility, sterilization failure, packaging failure and transportation damage.

The identified manufacturing process variation has been corrected through implementation of CAPA actions including:

Process revalidation, operator retraining, strengthened in-process inspection, enhanced quality monitoring and additional final product verification.

7.5 BENEFIT-RISK EVALUATION

The benefits of the medical device remain significant.

Benefits include:

Accurate medication delivery, safe administration of injectable medicines, sterile single-use design, reduced risk of cross contamination and compliance with intended clinical use.

Residual risks following implementation of corrective actions are considered acceptable and remain within the company's predefined risk acceptability criteria.

7.6 POST-MARKET SURVEILLANCE REVIEW

The company reviewed available post-market surveillance data covering distributed batches.

The review included:

1. Complaint records, customer feedback, distributor reports, vigilance reports, and adverse event monitoring.
2. Results demonstrated:
3. No increase in serious adverse events;
4. No reported patient deaths,
5. No permanent injury associated with the identified issue and no trend indicating unacceptable product risk.

7.7 RISK CONTROL MEASURES IMPLEMENTED

The following additional controls have been implemented:

1. 100% enhanced visual inspection, Increased sampling frequency
2. Reinforced process monitoring;
3. Additional operator competency assessment;
4. Strengthened line clearance procedures;
5. Increased QA oversight;
6. Revised work instructions;
7. Enhanced preventive maintenance schedule;
8. Intensified environmental monitoring;
9. Periodic effectiveness review of CAPA actions.

7.8 RESIDUAL RISK ASSESSMENT

Following implementation of all corrective actions:

1. Severity remains unchanged.
2. Probability of occurrence has been significantly reduced.

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3. Overall residual risk is classified as **Acceptable**.
4. No new hazards were introduced by the corrective actions.

7.9 BENEFIT-RISK CONCLUSION

Based on the investigation findings, CAPA implementation, verification activities, and updated risk analysis, Afrimedical Manufacturing and Supplies Limited concludes that:

1. The identified issue has been effectively controlled;
2. Implemented corrective actions are adequate to prevent recurrence;
3. Residual risks are acceptable;
4. The medical device continues to meet its intended purpose;
5. The overall benefit-risk profile remains favourable.

Accordingly, the affected products remain safe and effective when used in accordance with the Instructions for Use after completion of the Field Safety Corrective Action.

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SECTION 8
HEALTH HAZARD EVALUATION (HHE)
8.0 PURPOSE

The purpose of this Health Hazard Evaluation (HHE) is to provide a comprehensive clinical assessment of the potential health risks associated with the reported plunger withdrawal involving selected batches of Afriject Disposable Single-use Syringes.

This evaluation supports the Field Safety Corrective Action (FSCA), the revised Field Safety Notice (FSN), and the Risk Management File by determining:

The likelihood of patient harm, the potential severity of adverse clinical outcomes, the need for patient follow-up, the adequacy of the proposed corrective actions and the overall benefit-risk profile of the affected devices.

This HHE has been prepared in accordance with:

ISO 14971:2019, ISO/TR 24971:2020, ISO 13485:2016, WHO Guidance on Medical Device Vigilance, NAFDAC Medical Device Regulations and Afrimedical Risk Management Procedure

8.1 SCOPE

This Health Hazard Evaluation applies exclusively to the following products:

Product	Batch Number
Afriject Disposable Syringe 2 mL	500224002
Afriject Disposable Syringe 3 mL	500323037

The assessment covers all reasonably foreseeable clinical uses of the affected syringes in healthcare settings.

8.2 PRODUCT DESCRIPTION

Afriject Disposable Syringes are sterile, single-use medical devices intended for the administration and aspiration of medications and fluids.

The devices are commonly used in:

Hospitals, Primary Healthcare Centers, Clinics, Pharmacies, Emergency Departments, Immunization Programmes, and Surgical Units

8.3 DESCRIPTION OF THE REPORTED ISSUE

Post-market complaints indicated that, in isolated cases, the syringe plunger could separate completely from the barrel before or during intended use.

Potential consequences include:

Inability to administer medication, interruption of treatment, incomplete dose delivery, need to repeat the procedure and increased manipulation of sterile components.

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No confirmed deaths or serious patient injuries directly attributable to this issue had been identified at the time of this evaluation.

8.4 HEALTH HAZARD EVALUATION METHODOLOGY

The multidisciplinary Medical Review Team assessed the issue using the following process:

Review of complaint records, Review of retained sample testing, Review of manufacturing history, Review of complaint trends, Clinical evaluation of foreseeable hazards, Literature review of syringe malfunction consequences, Severity assessment, Probability assessment, Benefit-risk analysis and Determination of need for additional medical intervention.

8.5 CLINICAL HAZARD IDENTIFICATION

The following potential hazards were identified.

Hazard	Possible Clinical Consequence
Plunger withdrawal	Failure to complete medication administration
Treatment interruption	Delay in therapy
Under-dosing	Reduced therapeutic effect
Repeat injection	Increased patient discomfort
Loss of sterility	Local infection
Device replacement	Delay in emergency intervention
Additional manipulation	Needle injury to healthcare worker

8.6 CLINICAL SEVERITY ASSESSMENT

Negligible

Examples:

Syringe replaced immediately, No interruption of treatment and No patient injury

Clinical impact:

No medical intervention required.

Minor

Examples:

Slight delay in administration, Additional injection required and Temporary inconvenience

Clinical impact:

Minimal patient impact.

Moderate

Examples:

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Partial medication delivery, Repeat procedure required and Delay in treatment.

Clinical impact:

Temporary medical intervention.

Serious

Examples:

Delay involving critical medications, Failure to administer emergency drugs and Therapeutic failure requiring additional medical management,

Clinical impact:

Potential serious deterioration of health depending on the clinical setting.

Critical

Examples:

Emergency resuscitation, Intensive care medications and Life-support interventions.

Clinical impact:

Potential life-threatening consequence if no alternative syringe is immediately available.

8.7 CLINICAL PROBABILITY ASSESSMENT

Based on complaint trends, retained sample testing, and production review:

Probability	Assessment
Frequent	No
Probable	No
Occasional	No
Remote	Yes
Extremely Remote	Yes

Overall occurrence was assessed as **Low (Remote)**.

8.8 POPULATION RISK ASSESSMENT

Adult Patients

Potential impact:

Temporary treatment delay and Repeat injection,

Overall Risk:

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Low.

Paediatric Patients

Potential impact:

Increased distress due to repeat injection and Delay in medication administration.

Overall Risk:

Moderate.

Elderly Patients

Potential impact:

Delay in critical medication and Additional discomfort.

Overall Risk:

Moderate.

Emergency Patients

Potential impact:

Delay in life-saving therapy and Possible deterioration if replacement device unavailable.

Overall Risk:

Highest clinical concern.

Intensive Care Patients

Potential impact:

Delay in drug administration.

Overall Risk:

Moderate to Serious depending on medication involved.

Vaccination Programmes

Potential impact:

Interrupted vaccination and Requirement for replacement syringe.

Overall Risk:

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Low.

8.9 CLINICAL SCENARIOS

Scenario 1

Plunger withdraws before injection.

Clinical consequence:

No medication administered.

Action:

Replace syringe.

Residual risk:

Low.

Scenario 2

Plunger withdraws during injection.

Clinical consequence:

Incomplete dose delivered.

Action:

Clinical assessment.

Repeat dose if medically appropriate.

Residual risk:

Low.

Scenario 3

Healthcare worker attempts to reinsert plunger.

Clinical consequence:

Possible contamination.

Action:

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Discard device immediately.

Residual risk:

Low.

Scenario 4

Failure occurs during emergency treatment.

Clinical consequence:

Delay in administration.

Action:

Use replacement syringe immediately.

Residual risk:

Moderate.

8.10 HEALTHCARE PROFESSIONAL IMPACT

Healthcare professionals may experience:

Procedure interruption, Increased workload, Repeat medication preparation, Needle injury risk if improper handling occurs.

Training and updated instructions have been incorporated into the revised Field Safety Notice to minimize these risks.

8.11 PATIENT MONITORING REQUIREMENTS

Routine patient follow-up is **not required** solely because an affected syringe was used, provided:

medication was completely administered, no device malfunction occurred, no adverse clinical signs are present.

Patient assessment should be considered if:

Incomplete medication delivery is suspected, treatment delay occurred, a repeat dose may be clinically indicated, and contamination of the sterile pathway is suspected.

Clinical decisions remain the responsibility of the treating healthcare professional.

8.12 BENEFIT-RISK ASSESSMENT

Benefits of the device include:

Accurate medication administration, Sterile single-use design, Reduced cross-contamination risk and Wide availability in healthcare facilities.

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Risks identified:

Temporary interruption of treatment, Potential incomplete medication delivery, Need for replacement syringe.

Following implementation of the FSCA, customer notification, product replacement, and enhanced post-market surveillance, the Medical Review Team concluded that the **overall residual risk is acceptable** when balanced against the benefits of compliant replacement products.

8.13 MEDICAL MONITORING STRATEGY

Afrimedical will continue enhanced medical monitoring through:

Complaint trend analysis, distributor follow-up, healthcare facility feedback, adverse event review, periodic Medical Affairs review, quarterly reports to Management Review, regulatory reporting to NAFDAC where required.

8.14 CLINICAL RECOMMENDATIONS

The Medical Review Team recommends:

1. Completion of the Field Safety Corrective Action.
2. Continued product recall activities.
3. Replacement of all affected products.
4. Ongoing complaint monitoring for at least twelve months.
5. Continued review of complaint trends.
6. Annual review of the Risk Management File.
7. Immediate investigation of any new similar complaint.
8. Immediate notification of NAFDAC if the risk profile changes.

8.15 MEDICAL AFFAIRS CONCLUSION

Following a comprehensive review of the available clinical information, complaint history, retained sample testing, production records, and risk management documentation, the Medical Affairs Team concludes that:

1. The reported issue presents a **potential** risk of interrupted medication administration and treatment delay if it occurs during clinical use.
2. No confirmed evidence of a widespread manufacturing defect has been identified.
3. No confirmed deaths or serious injuries directly attributable to the reported issue had been identified during the review period.
4. The voluntary Field Safety Corrective Action implemented by Afrimedical is an appropriate and proportionate response to mitigate the identified risk.
5. The corrective actions, revised Field Safety Notice, enhanced complaint handling process, strengthened post-market surveillance activities, and CAPA programme are expected to reduce the residual risk to an acceptable level.
6. Continued monitoring through complaint trending, customer feedback, effectiveness verification, and periodic Management Review will ensure that any emerging safety concerns are identified promptly and managed appropriately.
7. Accordingly, the Medical Affairs Team supports the continuation of the FSCA until all affected products have been reconciled, replacement activities completed, effectiveness verified, and regulatory closure obtained from NAFDAC.

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8.16 APPROVAL

Name	Position	Signature	Date
Emerenini Kingsley	Quality Assurance Manager		27-07-2026
Olayinka Sulaiman	Regulatory Affairs Manager		27-07-2026
Gabi Al Aridi	General Manager		27-07-2026

8.17 OVERALL CONCLUSION

This Health Hazard Evaluation demonstrates that Afrimedical Manufacturing and Supplies Limited has conducted a structured, evidence-based clinical assessment consistent with ISO 14971:2019, ISO/TR 24971:2020, and NAFDAC regulatory expectations. The evaluation supports the implementation of the Field Safety Corrective Action, confirms the appropriateness of the risk control measures, and provides a documented clinical justification for the revised Field Safety Notice and associated CAPA programme.

The HHE forms an integral component of the overall regulatory response dossier and provides assurance that patient safety considerations have been systematically evaluated and addressed.

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SECTION 9

QUALITY MANAGEMENT SYSTEM (QMS) ENHANCEMENT REPORT, MANAGEMENT REVIEW, INTERNAL AUDIT, AND CONTINUAL IMPROVEMENT PLAN

Response to NAFDAC Review of the Field Safety Notice (FSN)

9.0 PURPOSE

This section documents the systematic improvements made to the Afrimedical Quality Management System (QMS) following the Field Safety Corrective Action (FSCA). The enhancements demonstrate the organization's commitment to continual improvement and regulatory compliance in accordance with:

ISO 13485:2016, ISO 14971:2019, NAFDAC Medical Device Regulations, Good Manufacturing Practice (GMP) and Afrimedical Quality Manual

These improvements are intended to ensure that lessons learned from the investigation are incorporated into routine operations and that similar issues are prevented or detected earlier.

9.1 EXECUTIVE MANAGEMENT COMMITMENT

Top Management acknowledges its responsibility for ensuring that the Quality Management System remains suitable, adequate, and effective.

Management has therefore committed to:

1. Providing sufficient financial and human resources.
2. Supporting implementation of all CAPA(s).
3. Ensuring regulatory compliance.
4. Strengthening quality culture.
5. Reviewing quality performance regularly.
6. Monitoring post-market surveillance.
7. Promoting proactive risk management.
8. Supporting continual improvement.

Management has reaffirmed that **patient safety remains the highest organizational priority**.

9.2 QUALITY MANAGEMENT SYSTEM ENHANCEMENT PROGRAMME

A structured QMS Improvement Programme was initiated immediately following the FSCA.

The programme comprised:

Improvement Area	Objective	Status
Complaint Handling	Improve early detection of trends	Completed
CAPA	Strengthen root cause investigations	Completed
Risk Management	Improve integration with PMS	Completed
Recall Procedure	Standardize recall execution	Completed

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Supplier Controls	Enhance component quality assurance	Completed
Training	Improve staff competency	Completed
Internal Audits	Increase audit frequency	Ongoing
Management Review	Strengthen quality oversight	Completed

9.3 MANAGEMENT REVIEW

A special Management Review meeting was convened to evaluate the FSCA and its impact on the Quality Management System.

Agenda

Summary of field complaints, Investigation findings, Health Hazard Evaluation, Risk Management Report, CAPA implementation, Recall progress, Complaint trends, Regulatory communications, Resource requirements and Opportunities for improvement.

Decisions

Senior Management approved:

Continued implementation of the FSCA, Revision of all applicable SOPs, Expansion of complaint trend analysis, Additional staff training, Strengthening of supplier monitoring, Increased frequency of internal audits, Quarterly review of post-market surveillance and Annual review of the Risk Management File.

9.4 SOP REVIEW AND REVISION PROGRAMME

The following Standard Operating Procedures (SOPs) were reviewed and updated:

SOP	Revision
Complaint Handling Procedure	Updated
CAPA Procedure	Updated
Recall Procedure	Updated
Field Safety Corrective Action Procedure	Updated
Risk Management Procedure	Updated
Post-Market Surveillance Procedure	Updated
Management Review Procedure	Updated
Internal Audit Procedure	Updated
Supplier Evaluation Procedure	Updated
Distribution Traceability Procedure	Updated
Customer Feedback Procedure	Updated
Document Control Procedure	Updated

Each revised SOP was reviewed, approved, and communicated to relevant personnel through controlled document distribution.

9.5 INTERNAL AUDIT PROGRAMME

The Internal Audit Programme was enhanced to verify sustained implementation of corrective actions.

Audit Scope

Complaint Handling, CAPA Management, Risk Management, Product Traceability, Complaint Trending, Recall Process, Post-Market Surveillance, Document Control, Supplier Controls and Production Controls

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Audit Frequency

Process	Frequency
Complaint Handling	Quarterly
CAPA	Quarterly
Recall Management	Annually or Following Each FSCA
Risk Management	Annually
Production	Quarterly
Warehouse	Quarterly
Regulatory Affairs	Quarterly
Supplier Management	Annually

Audit findings are tracked to closure through the CAPA system.

9.6 COMPETENCY, TRAINING AND AWARENESS

A comprehensive training programme was conducted to ensure that all relevant personnel understood the revised procedures and regulatory expectations.

Training Topics

Complaint Management, Medical Device Vigilance, ISO 13485:2016 Requirements, ISO 14971:2019 Risk Management, Field Safety Corrective Actions, Product Recall Procedures, CAPA Methodology, Root Cause Analysis, Regulatory Reporting and Good Documentation Practices (GDP)

Competency Verification

Competency was verified through:

Practical demonstrations, Observation of work practices and Supervisor evaluations.

Training records are maintained in accordance with the Document Control Procedure.

9.7 SUPPLIER QUALITY IMPROVEMENT PROGRAMME

Although the investigation did not identify supplier non-conformities, Afrimedical implemented additional supplier controls to strengthen oversight.

Actions included:

Enhanced supplier performance reviews, Increased incoming inspection of critical components, Periodic supplier audits, Review of Certificates of Analysis (CoAs), Verification of material specifications, Strengthened change notification requirements and Annual supplier risk assessments.

Critical suppliers are now subject to a risk-based monitoring programme.

9.8 PRODUCTION PROCESS REVIEW

Production processes associated with syringe assembly were reviewed to confirm continued process capability.

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The review included:

Verification of validated process parameters, Review of assembly line controls, Review of in-process inspections, Assessment of process capability data, Review of batch manufacturing records, Confirmation of preventive maintenance and Verification of operator training.

No systemic process deficiencies were identified.

9.9 EQUIPMENT QUALIFICATION AND CALIBRATION REVIEW

All equipment associated with the manufacture and testing of the affected syringes was reviewed.

Verification included:

Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Calibration certificates, Preventive maintenance records, Equipment logbooks, Performance verification,

All reviewed equipment remained within validated operating parameters.

9.10 ENVIRONMENTAL MONITORING REVIEW

Environmental monitoring records were reviewed for the production periods associated with the affected batches.

The review covered:

Airborne particulate monitoring, Microbiological monitoring, Differential pressure, Temperature, Relative humidity, Cleaning verification and Personnel monitoring,

No abnormal environmental trends were identified.

9.11 COMPLAINT HANDLING SYSTEM IMPROVEMENTS

The complaint handling process was strengthened through:

Immediate electronic complaint registration, Automated escalation for safety-related complaints, Monthly trend analysis, Integration with CAPA, Integration with Risk Management, Improved response timelines and Enhanced customer feedback mechanisms.

A complaint dashboard has been introduced to monitor trends in real time.

9.12 CAPA EFFECTIVENESS REVIEW

The CAPA programme is reviewed monthly using defined performance indicators.

Key Indicators

KPI	Target
CAPA(s) completed on time	≥95%
Recurrence of similar issue	0
Complaint closure within target	≥95%
CAPA verification completed	100%

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Internal audit findings closed within target	≥95%
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Any CAPA found to be ineffective is reopened and subjected to further investigation.

9.13 POST-MARKET SURVEILLANCE ENHANCEMENTS

The Post-Market Surveillance (PMS) programme has been expanded to include:

Monthly complaint trend reviews, Enhanced distributor engagement, Structured customer surveys, Periodic field performance evaluations, Review of global vigilance information where applicable, and Quarterly PMS reports to Management Review.

Findings are incorporated into the Risk Management File and CAPA system.

9.14 QUALITY OBJECTIVES AND KEY PERFORMANCE INDICATORS

The following quality objectives have been established:

Objective	KPI	Target
Improve complaint responsiveness	Initial assessment within 24 hours	100%
Improve complaint closure	Closure within 30 days	≥95%
Enhance traceability	Product reconciliation	≥98%
Strengthen supplier quality	Approved supplier performance	≥95%
Improve training compliance	Staff competency completion	100%
Strengthen CAPA	On-time implementation	≥95%
Maintain regulatory compliance	Reportable events submitted within required timelines	100%

Performance against these objectives will be reviewed during each Management Review meeting.

9.15 CONTINUAL IMPROVEMENT PROGRAMME

Afrimedical has established a structured continual improvement programme that includes:

Quarterly Quality Review Meetings, Annual Risk Management Review, Annual SOP review cycle, Annual internal audit programme, Supplier development initiatives, Customer feedback analysis, Bench-marking against regulatory best practices and Periodic management review of quality metrics.

Improvement opportunities are documented, prioritized based on risk, and tracked through the CAPA system.

9.16 MANAGEMENT DECLARATION

Top Management confirms that:

1. All identified corrective and preventive actions have been appropriately initiated.
2. The Quality Management System has been strengthened in response to the reported issue.
3. Adequate resources have been allocated to sustain the improvements.
4. Patient safety and regulatory compliance remain the highest priorities.
5. The effectiveness of the implemented improvements will be monitored through internal audits, Management Review, and post-market surveillance.
6. Afrimedical will continue to cooperate fully with NAFDAC and provide any additional information required during the review and closure of the Field Safety Corrective Action.

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9.17 CONCLUSION

The Quality Management System enhancements described in this section demonstrate Afrimedical Manufacturing and Supplies Limited's commitment to continual improvement and to maintaining a robust medical device quality system. The actions implemented following the FSCA have strengthened complaint handling, CAPA management, risk management, supplier oversight, training, post-market surveillance, and executive oversight.

These improvements provide objective evidence that the organization has addressed the underlying quality system gaps identified during the regulatory review and has established sustainable mechanisms to prevent recurrence and support ongoing compliance with ISO 13485:2016, ISO 14971:2019, and NAFDAC Medical Device Regulations.

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SECTION 10

TECHNICAL EVIDENCE, MANUFACTURING RECORD REVIEW, TEST REPORTS, AND OBJECTIVE EVIDENCE SUPPORTING THE FIELD SAFETY CORRECTIVE ACTION (FSCA)

Response to NAFDAC Review of the Field Safety Notice (FSN)

10.0 PURPOSE

This section provides the objective technical evidence supporting Afrimedical Manufacturing and Supplies Limited's investigation into the reported plunger withdrawal complaints and demonstrates that the investigation extended beyond complaint review to include manufacturing, quality control, engineering, sterilization, environmental monitoring, supplier quality, and post-market surveillance.

This Chapter serves as documentary evidence that the conclusions presented in Section 2–9 are supported by verified manufacturing and quality records.

10.1 OBJECTIVE EVIDENCE MATRIX

Evidence Category	Records Reviewed	Result
Batch Manufacturing Records	Complete	No critical deviations
Device History Records	Complete	Acceptable
Raw Material Records	Complete	Materials met specifications
Incoming Inspection	Complete	Accepted
Sterilization Records	Complete	Cycle accepted
Calibration Records	Complete	Equipment within calibration
Environmental Monitoring	Complete	Acceptable
Complaint Investigation	Complete	Reviewed
Retained Sample Testing	Completed	Passed specifications
Distribution Records	Complete	Traceability confirmed

10.2 MANUFACTURING RECORD REVIEW

The Manufacturing Investigation Team reviewed all production documentation for the affected batches.

The review covered:

Production planning records, Batch issue records, Line clearance documentation, Operator identification, In-process inspection records, Production yield reports, Nonconformance reports, Process deviation reports, Production logbooks and Shift handover records.

Findings

1. Manufacturing activities were completed in accordance with approved procedures.
2. No unauthorized process changes were identified.
3. No critical production deviations were recorded.
4. Production yields remained within validated limits.
5. Production documentation was complete and properly approved.

Conclusion: Manufacturing records do not indicate evidence of a systemic production failure.

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10.3 DEVICE HISTORY RECORD (DHR) REVIEW

The Device History Records were reviewed to confirm compliance with the approved manufacturing process.

The review confirmed:

Correct product identification, Approved production route. Complete traceability, Acceptance of all manufacturing stages, Correct packaging configuration, Sterilization release authorization, and Final Quality Assurance approval.

No discrepancies affecting product safety were identified.

10.4 BATCH MANUFACTURING RECORD (BMR) REVIEW

The following manufacturing records were examined:

Record	Status
Raw material issue	Verified
Component reconciliation	Verified
Production quantities	Verified
Process parameters	Within limits
Assembly records	Acceptable
Visual inspection	Acceptable
Final inspection	Passed
Batch release	Approved

No unexplained discrepancies were identified.

10.5 RAW MATERIAL REVIEW

Critical raw materials reviewed included:

Polypropylene resin, Stainless steel needles, Packaging materials and Sterile barrier materials

The review confirmed:

Approved suppliers, Valid Certificates of Analysis (CoAs), Incoming inspection acceptance and Supplier approval status maintained,

No supplier change during manufacture of the affected batches.

10.6 INCOMING QUALITY CONTROL REVIEW

Incoming inspection records demonstrated compliance with approved specifications.

Verified Parameters

Dimensional conformity, Visual appearance, Material certification, Sampling plan, Acceptance criteria., and Lot identification.

All materials met established acceptance criteria.

10.7 PROCESS VALIDATION REVIEW

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The Process Validation Team reviewed validation documentation for:

Injection moulding, Component assembly, Plunger insertion, Needle attachment, Packaging and Sterilization.

Findings

1. All validation protocols had been previously approved.
2. No outstanding re-validation requirements existed.
3. No process drift was identified.
4. Critical process parameters remained within validated ranges.

10.8 FINISHED PRODUCT RELEASE REVIEW

Quality Control verified that each affected batch successfully completed release testing before market distribution.

Release Tests Reviewed

Test	Result
Visual inspection	Passed
Graduation accuracy	Passed
Leakage test	Passed
Plunger movement	Passed
Dead space verification	Passed
Dimensional inspection	Passed
Sterility release	Passed
Packaging integrity	Passed

All release criteria were met.

10.9 RETAINED SAMPLE INVESTIGATION

Retained samples from the affected batches were retrieved under controlled conditions and subjected to additional testing.

Additional Testing Performed

Visual examination, Functional testing, Plunger retention force, Barrel dimensional verification, Leakage test. Air tightness, Smoothness of plunger movement and Luer fit verification.

Results

No abnormal observations were reproduced during laboratory testing.

The retained samples met the approved product specifications.

10.10 LABORATORY INVESTIGATION REPORT

The Quality Control Laboratory expanded routine testing to include comparative analysis of retained samples from adjacent production batches.

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The investigation demonstrated:

No statistically significant differences in plunger retention force, No measurable deterioration in dimensional tolerances, No evidence of material degradation, No increase in leakage rates, and No reduction in functional performance.

The reported field condition could not be reproduced under controlled laboratory conditions.

10.11 EQUIPMENT QUALIFICATION AND CALIBRATION REVIEW

Engineering reviewed all equipment associated with manufacture and testing.

Equipment Reviewed

Equipment	Status
Injection moulding machines	Qualified
Assembly machines	Qualified
Packaging machines	Qualified
Leak tester	Calibrated
Dimensional gauges	Calibrated
Force tester	Calibrated
Environmental monitors	Calibrated

No overdue calibrations or qualification deficiencies were identified.

10.12 STERILIZATION VALIDATION REVIEW

Sterilization records were reviewed for the affected batches.

Verification included:

Cycle parameters, Biological indicator results, Chemical indicator records, Sterilization load configuration, Validation protocol and Sterility Assurance Level (SAL) verification

All sterilization cycles met approved acceptance criteria and were released by Quality Assurance.

10.13 ENVIRONMENTAL MONITORING REVIEW

Cleanroom monitoring data covering the production periods of the affected batches were reviewed.

Parameters Evaluated

Airborne particulate counts, Viable microbial counts, Differential pressure, Temperature, Relative humidity, Cleaning records. and Personnel monitoring.

Trend analysis did not identify abnormal environmental conditions that could have contributed to the reported issue.

10.14 PACKAGING VALIDATION REVIEW

Packaging records confirmed:

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1. Packaging materials complied with approved specifications.
2. Seal integrity testing met acceptance criteria.
3. Packaging validation remained current.
4. Transportation validation remained valid.
5. Storage conditions were maintained throughout warehouse operations.
6. No packaging deficiencies were identified.

10.15 DISTRIBUTION TRACEABILITY REVIEW

Distribution records were reconciled against production quantities.

Verification included:

Warehouse dispatch records, Distributor shipment records, Customer delivery records, Returned product reconciliation and Replacement product records.

Complete traceability of affected batches was demonstrated.

10.16 COMPLAINT TREND ANALYSIS

Complaint data covering the preceding twenty-four (24) months were reviewed.

Trending Categories

Leakage, Plunger movement, Graduation accuracy, Needle attachment, Packaging defects, Sterility complaints and Mechanical failures,

No sustained upward trend in plunger-related complaints was identified prior to the current reports.

Following implementation of the FSCA, enhanced monthly trend analysis was initiated.

10.17 STATISTICAL REVIEW

The investigation included statistical evaluation of:

Complaint frequency, Complaint rate per units distributed, Batch-to-batch variability, Product release test results and Retained sample measurements.

The analysis did not demonstrate evidence of statistically significant process deterioration associated with the affected batches.

10.18 OVERALL TECHNICAL INVESTIGATION SUMMARY

The technical investigation demonstrated that:

Manufacturing records were complete and compliant, Raw materials met approved specifications, Production processes remained validated, Equipment remained qualified and calibrated, Sterilization processes were compliant, Environmental conditions remained within limits, Finished products met release specifications, Retained samples passed all additional testing, Distribution traceability was fully maintained and Complaint trends did not indicate a systemic manufacturing issue.

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Nevertheless, Afrimedical implemented a precautionary Field Safety Corrective Action to ensure patient safety while continuing enhanced post-market surveillance.

10.19 REGULATORY DECLARATION

Afrimedical Manufacturing and Supplies Limited certifies that the technical evidence presented in this section accurately reflects the investigation undertaken in response to the reported field complaints. The investigation was conducted by qualified personnel using approved procedures and objective evidence generated under the company's ISO 13485:2016 Quality Management System.

Afrimedical confirms that:

1. All relevant manufacturing and quality records were reviewed.
2. The investigation was conducted without bias and with full consideration of patient safety.
3. The conclusions presented are supported by documented evidence.

All identified regulatory commitments will continue to be monitored through the CAPA programme, Management Review, and enhanced post-market surveillance.

Any new information that could affect the risk profile of the affected products will be promptly assessed and reported to NAFDAC in accordance with applicable regulatory requirements.

10.20 CONCLUSION

This section provides the objective technical evidence supporting Afrimedical's comprehensive response to the Field Safety Corrective Action. The review of manufacturing records, quality control data, validation activities, retained sample testing, environmental monitoring, equipment qualification, and complaint trends demonstrates that a systematic and risk-based investigation was performed.

The evidence supports the conclusion that, while no definitive systemic manufacturing defect was identified, the voluntary FSCA, enhanced surveillance, and comprehensive CAPA programme represent appropriate and proportionate measures to protect patients, healthcare professionals, and the integrity of the medical device supply chain.

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SECTION 11

REGULATORY ANNEXES, SUPPORTING DOCUMENTATION, CONTROLLED FORMS, TRACEABILITY RECORDS AND REGULATORY TEMPLATES

Response to NAFDAC Review of the Field Safety Notice (FSN)

11.0 PURPOSE

This section contains all supporting regulatory annexes, controlled forms, templates, records, logs and certifications referenced throughout Section 1–10.

These annexes constitute the operational documentation required to implement, document, monitor and verify the effectiveness of the Field Safety Corrective Action (FSCA) and facilitate regulatory review by NAFDAC.

11.1 ANNEX INDEX

Annex	Document
A	Final Revised Field Safety Notice
B	Customer Acknowledgement Form
C	Distributor Confirmation Form
D	Product Recall Response Form
E	Return Material Authorization Form
F	Product Reconciliation Log
G	Healthcare Facility Confirmation
H	Adverse Event Reporting Form
I	Complaint Investigation Form
J	CAPA Record
K	Root Cause Investigation Report
L	Effectiveness Verification Report
M	Product Traceability Matrix
N	Distribution Register
O	Recall Progress Report
P	Internal Audit Checklist
Q	Management Review Certification
R	Executive Declaration

ANNEX A

FINAL REVISED FIELD SAFETY NOTICE

Document Number:
AFR/FSN/2026/001

Revision:
01

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SUBJECT

Urgent Field Safety Notice

Afriject Disposable Syringe

Affected Batches: 500224002, 500323037

Reason for Notice

Reports of plunger withdrawal during intended use.

Required Actions

- ✓ Stop use immediately
- ✓ Quarantine stock
- ✓ Notify users
- ✓ Complete acknowledgement
- ✓ Return affected stock
- ✓ Report adverse events

Contact Information

Afrimedical Customer Care

Afrimedical Manufacturing and Supplies Limited

Telephone: 070030303030

Email: customercare@afri-medical.com

Available 24 hours during recall implementation.

ANNEX B

CUSTOMER ACKNOWLEDGEMENT FORM

Document Number:
AFR/FSN/2026/002

Revision:
01

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Customer Name

Address

Contact Person

Telephone

Email

Products Received

Batch Numbers

Quantity Received

Quantity Remaining

Quantity Used

Quantity Quarantined

Date Notice Received

Signature

Company Stamp

ANNEX C

DISTRIBUTOR ACKNOWLEDGEMENT

Document Number:
AFR/FSN/2026/003

Revision:
01

Distributor

Responsible Officer

Date FSN Received

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Date Customers Notified

Number of Customers Contacted

Outstanding Customers

Product Remaining

Product Returned

Remarks

Signature

ANNEX D

PRODUCT RECALL RESPONSE FORM

Document Number:
AFR/FSN/2026/004

Revision:01

Customer

Product

Batch

Quantity Received

Quantity Used

Quantity Remaining

Quantity Returned

Replacement Required

Collection Date

Receiving Officer

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ANNEX E

RETURN MATERIAL AUTHORIZATION (RMA)

Document Number:
AFR/FSN/2026/005

Revision:01

RMA Number

Customer

Distributor

Product

Batch Number

Reason for Return

Quantity

Collection Date

Courier

Received By

Inspection Result

Disposition

ANNEX F

PRODUCT RECONCILIATION LOG

Document Number:
AFR/FSN/2026/006

Revision:01

Item	Quantity
Manufactured	
Released	

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Warehouse Stock	
Distributed	
Returned	
Replaced	
Destroyed	
Outstanding	

ANNEX G

HEALTHCARE FACILITY CONFIRMATION

Document Number:
AFR/FSN/2026/007

Revision:01

Hospital Name

Department

Affected Stock Located

YES / NO

Stock Quarantined

YES / NO

Departments Notified

YES / NO

Products Returned

YES / NO

Completed By

Date

ANNEX H

MEDICAL DEVICE ADVERSE EVENT REPORT

Document Number:
AFR/FSN/2026/008

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Revision:01

Incident Number

Hospital

Date

Product

Batch

Description

Patient Outcome

Medical Intervention

Reporter

Telephone

Email

Submitted to NAFDAC

YES / NO

ANNEX I

COMPLAINT INVESTIGATION FORM

Document Number:
AFR/FSN/2026/009

Revision:01

Complaint Number

Customer

Product

Batch

Date Received

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Description

Classification

Critical

Major

Minor

Investigation Team

Evidence Reviewed

Root Cause

Corrective Action

Preventive Action

Closure Date

Approval

ANNEX J

CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Document Number:
AFR/FSN/2026/010

Revision:01

CAPA Number

Source

Complaint

Audit

Recall

Supplier

Description

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Containment Action

Root Cause

Corrective Action

Preventive Action

Owner

Target Date

Verification

Effectiveness Review

Closure Approval

ANNEX K

ROOT CAUSE INVESTIGATION REPORT

Document Number:
AFR/FSN/2026/011

Revision:01

Problem Description

Investigation Method

5 Why Analysis

Fishbone Analysis

Evidence Reviewed

Manufacturing Review

Supplier Review

Laboratory Findings

Risk Assessment

Conclusion

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Recommendations

Approvals

ANNEX L

EFFECTIVENESS VERIFICATION REPORT

Document Number:
AFR/FSN/2026/012

Revision:01

Recall Objective

Performance Indicator

Target

Actual Result

Customer Response Rate

Product Recovery Rate

Product Replacement Rate

Complaint Recurrence

Training Completion

Audit Verification

Overall Conclusion

Approved By

ANNEX M

PRODUCT TRACEABILITY MATRIX

Document Number:
AFR/FSN/2026/013

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Stage		Record
Raw Material Receipt		Material Lot
Incoming Inspection		Inspection Record
Production		Batch Number
Assembly		Work Order
Sterilization		Load Number
Packaging		Packaging Lot
Warehouse		Warehouse Register
Distribution		Delivery Record
Customer		Delivery Confirmation
Recall		Return Register

ANNEX N

DISTRIBUTION REGISTER

Document Number:
AFR/FSN/2026/014

Revision:01

Customer

Address

Invoice Number

Delivery Date

Product

Batch

Quantity

Telephone

Recall Status

Replacement Status

Remarks

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ANNEX O

FSCA PROGRESS REPORT

Document Number:
AFR/FSN/2026/015

Revision:01

Week Number

Customers Contacted

Acknowledgements Received

Products Returned

Products Outstanding

Replacement Completed

Outstanding Investigations

Issues Requiring Escalation

Prepared By

Approved By

ANNEX P

INTERNAL AUDIT CHECKLIST

Document Number:
AFR/FSN/2026/016

Revision:01

Complaint Handling

- ☐ Complaint recorded
- ☐ Investigation initiated

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- ☐ Classification correct
- ☐ CAPA opened
- ☐ Closure documented

Recall

- ☐ FSN issued
- ☐ Customer notified
- ☐ Product quarantined
- ☐ Product returned
- ☐ Product reconciled
- ☐ Replacement completed

CAPA

- ☐ Root cause adequate
- ☐ Actions completed
- ☐ Verification complete
- ☐ Effectiveness demonstrated

Risk Management

- ☐ Risk file updated
- ☐ Residual risk evaluated
- ☐ Management approval

ANNEX Q

MANAGEMENT REVIEW CERTIFICATION

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Document Number:
AFR/FSN/2026/017

Revision:01

The Executive Management of Afrimedical Manufacturing and Supplies Limited hereby certifies that:

The Field Safety Corrective Action has been reviewed, adequate resources have been provided, CAPA(s) have been approved, risks have been evaluated, regulatory obligations are being fulfilled, effectiveness monitoring has been established and continual improvement activities have been initiated,

Signed

General Manager

Date

ANNEX R

EXECUTIVE DECLARATION

Document Number:
AFR/FSN/2026/018

Revision:01

Afrimedical Manufacturing and Supplies Limited certifies that:

1. All information submitted within this regulatory response dossier is true and accurate.
2. All investigations were performed in accordance with approved procedures.
3. The company has implemented all corrective and preventive actions described in this submission.
4. The Field Safety Corrective Action is being implemented in accordance with ISO 13485:2016 and NAFDAC requirements.
5. All affected customers have been notified.
6. Product traceability has been maintained.
7. Regulatory reporting obligations will continue until formal closure.
8. Any additional safety information identified following submission will be communicated promptly to NAFDAC.

Signed

General Manager

Afrimedical Manufacturing and Supplies Limited

Company Seal

Date

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11.2 MASTER DOCUMENT REGISTER

Document No.	Document Title	Revision	Status
AFR/QA/REG/FSCA/001	Regulatory Response Letter	01	Approved
AFR/QA/REG/FSCA/002	Root Cause Investigation Report	01	Approved
AFR/QA/REG/FSCA/003	CAPA Report	01	Approved
AFR/QA/REG/FSCA/004	Risk Management File	01	Approved
AFR/QA/REG/FSCA/005	Health Hazard Evaluation	01	Approved
AFR/QA/REG/FSCA/006	Revised Field Safety Notice	02	Approved
AFR/QA/REG/FSCA/007	Recall Strategy	01	Approved
AFR/QA/REG/FSCA/008	Post-Market Surveillance Plan	01	Approved
AFR/QA/REG/FSCA/009	Effectiveness Verification Plan	01	Approved

11.3 DOSSIER CROSS-REFERENCE MATRIX

NAFDAC Observation	Supporting section	Supporting Annex
Field Safety Notice deficiencies	Vol. 6	Annex A
Risk Assessment	Vol. 7	Annex K
Health Hazard Evaluation	Vol. 8	Annex H
QMS Improvements	Vol. 9	Annex P & Q
Technical Investigation	Vol. 10	Annex M
CAPA Implementation	Vol. 4	Annex J
Recall Activities	Vol. 5	Annex D, E, F
Traceability	Vol. 5 & 10	Annex M & N
Regulatory Communication	Vol. 1 & 6	Annex A

11.4 RECORD RETENTION REQUIREMENTS

All records generated as part of the FSCA shall be retained under document control in accordance with Afrimedical's Record Control Procedure and applicable regulatory requirements.

Record Type	Minimum Retention Period
Complaint Files	10 years
CAPA Records	10 years
Recall Documentation	10 years
Distribution Records	10 years
Risk Management File	Product lifetime + regulatory retention period
Management Review Records	10 years
Internal Audit Reports	10 years
Customer Communications	10 years

11.5 CONCLUSION

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This section provides the complete set of controlled regulatory annexes, operational templates, and documentary evidence required to support the implementation and verification of the Field Safety Corrective Action. Together with Section 1 through 10, these annexes demonstrate a comprehensive and well-documented quality system response consistent with ISO 13485:2016, ISO 14971:2019, Good Manufacturing Practice (GMP), and NAFDAC Medical Device regulatory expectations.

The annexes are intended to facilitate regulatory review, support inspection readiness, ensure traceability, and provide standardized records for execution, monitoring, and closure of the FSCA.

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SECTION 12

EXECUTIVE REGULATORY CLOSE-OUT REPORT

FINAL RESPONSE TO NAFDAC OBSERVATIONS ON THE FIELD SAFETY NOTICE (FSN) AND FIELD SAFETY CORRECTIVE ACTION (FSCA)

12.1 EXECUTIVE SUMMARY

Afrimedical Manufacturing and Supplies Limited respectfully submits this Executive Regulatory Close-Out Report as the final section of the response dossier prepared following the review of the Field Safety Notice (FSN) and the implementation of a voluntary Field Safety Corrective Action (FSCA) concerning specific batches of Afriject Disposable Syringes.

The objective of this submission is to demonstrate that:

1. All observations communicated by NAFDAC have been systematically addressed.
2. Appropriate corrective and preventive actions (CAPAs) have been implemented.
3. A structured risk management process compliant with ISO 14971:2019 has been applied.
4. Health hazard evaluations have confirmed that the residual risk is acceptable following implementation of the FSCA.
5. The Quality Management System has been strengthened to prevent recurrence.
6. The FSCA has been executed in accordance with applicable regulatory and quality management requirements.

The complete dossier consists of twelve integrated Section, each providing documentary evidence supporting Afrimedical's commitment to patient safety, product quality, and regulatory compliance.

12.2 BACKGROUND

Following post-market complaints concerning possible plunger separation in selected batches of Afriject Disposable Syringes, Afrimedical voluntarily initiated a Field Safety Corrective Action (FSCA) and notified NAFDAC.

Subsequently, NAFDAC reviewed the initial Field Safety Notice and recommended that additional information and supporting evidence be provided to ensure that:

The risk evaluation was comprehensive, customer communications were strengthened, product traceability was fully documented, recall effectiveness could be objectively demonstrated and the Quality Management System adequately supported the corrective actions.

This dossier has been prepared to comprehensively address those recommendations.

12.3 PURPOSE OF THE SUBMISSION

This submission is intended to:

1. Respond to all NAFDAC observations.
2. Provide objective evidence supporting Afrimedical's investigation.
3. Demonstrate the implementation and effectiveness of CAPAs.
4. Confirm that affected products have been managed through a structured FSCA.
5. Demonstrate compliance with applicable regulatory requirements.
6. Request regulatory acceptance of the implemented actions.

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12.4 OVERVIEW OF THE FIELD SAFETY CORRECTIVE ACTION

The FSCA included the following activities:

1. Immediate notification to NAFDAC.
2. Issuance of a revised Field Safety Notice.
3. Customer notification.
4. Distributor notification.
5. Product traceability verification.
6. Product quarantine.
7. Product reconciliation.
8. Product return.
9. Replacement of affected products.
10. Complaint investigation.
11. Root cause analysis.
12. Risk assessment.
13. Health Hazard Evaluation.
14. CAPA implementation.
15. Effectiveness verification.
16. Enhanced post-market surveillance.

The FSCA was executed under the oversight of the Executive FSCA Committee.

12.5 SUMMARY OF INVESTIGATIONS

A cross-functional investigation was conducted involving Quality Assurance, Regulatory Affairs, Production, Engineering, Quality Control, Medical Affairs, and Supply Chain.

The investigation included:

Investigation Area	Outcome
Complaint Review	Completed
Manufacturing Record Review	No critical deviations identified
Device History Record Review	Complete and compliant
Batch Manufacturing Record Review	No unexplained discrepancies
Retained Sample Testing	Met approved specifications
Equipment Qualification	Confirmed current
Calibration Review	Up to date
Environmental Monitoring	Within established limits
Sterilization Validation	Successfully verified
Supplier Review	Approved supplier status confirmed
Risk Management	Updated and approved
Health Hazard Evaluation	Completed

The investigation did not identify evidence of a systemic manufacturing defect. Nevertheless, the voluntary FSCA was maintained as a precautionary measure to protect patient safety.

12.6 SUMMARY OF CORRECTIVE AND PREVENTIVE ACTIONS

The following CAPAs were implemented:

Immediate Actions

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1. Distribution suspended for affected batches.
2. Affected stock quarantined.
3. Customers notified.
4. NAFDAC informed.
5. Internal investigation initiated.

Corrective Actions

1. Revised Field Safety Notice issued.
2. Recall procedures strengthened.
3. Complaint handling process enhanced.
4. Traceability process improved.
5. Additional retained sample testing completed.
6. Product replacement programme implemented.

Preventive Actions

1. SOP revisions.
2. Enhanced post-market surveillance.
3. Expanded risk management activities.
4. Increased internal audit frequency.
5. Additional staff training.
6. Supplier quality monitoring enhancement.
7. Strengthened Management Review process.

12.7 NAFDAC OBSERVATION RESPONSE MATRIX

S/N	NAFDAC Observation	Afrimedical Response	Supporting Section
1	FSN required additional detail	Revised FSN issued	Section 6
2	Risk assessment required strengthening	ISO 14971 Risk Management File completed	Section 7
3	Clinical assessment required	Health Hazard Evaluation completed	Section 8
4	QMS improvements required	QMS enhancement programme implemented	Section 9
5	Technical evidence requested	Manufacturing and laboratory records reviewed	Section 10
6	Supporting documentation required	Regulatory annexes prepared	Section 11
7	CAPA effectiveness required	Verification completed	Section 4, 9 and 11
8	Recall effectiveness required	Product reconciliation and monitoring completed	Section 5 and 11

12.8 EFFECTIVENESS VERIFICATION

Afrimedical evaluated the effectiveness of the implemented actions using predefined performance indicators.

Performance Indicator	Target	Status
Customer notification	100%	Achieved
Distributor notification	100%	Achieved
Product traceability	≥98%	Achieved

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Product reconciliation	≥98%	Achieved
CAPA implementation	100%	Achieved
Staff training completion	100%	Achieved
SOP revision	100%	Achieved
Risk Management File update	100%	Achieved
Management Review completion	100%	Achieved

Effectiveness verification demonstrated that the corrective actions were implemented as planned and that the quality system improvements have been integrated into routine operations.

12.9 RECALL PERFORMANCE SUMMARY

The FSCA was monitored through a structured effectiveness programme.

Illustrative Performance Metrics

Activity	Result
Customer acknowledgements received	98.5%
Product reconciliation completed	99.1%
Affected stock recovered	97.8%
Replacement products supplied	100% of recovered units
Outstanding investigations	0

12.10 BENEFIT–RISK ASSESSMENT

The multidisciplinary review concluded that:

1. The issue was limited to identified batches.
2. The voluntary FSCA significantly reduced potential patient risk.
3. Enhanced traceability and communication ensured rapid identification of affected products.
4. No new information emerged that altered the overall risk profile during the review period.
5. The benefits of supplying compliant replacement products outweighed the residual risks following implementation of the corrective actions.

Accordingly, the overall benefit–risk profile remains favourable.

12.11 MANAGEMENT COMMITMENT

Top Management confirms its ongoing commitment to:

1. Maintaining an effective ISO 13485-compliant Quality Management System.
2. Ensuring compliance with NAFDAC regulations and applicable international standards.
3. Supporting post-market surveillance and vigilance activities.
4. Maintaining effective complaint handling and CAPA systems.
5. Promoting continual improvement and patient safety.
6. Necessary resources have been allocated to sustain the improvements described in this dossier.

12.12 REGULATORY DECLARATION

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Afrimedical Manufacturing and Supplies Limited hereby declares that:

1. The information contained in this dossier is accurate to the best of the company's knowledge.
2. The investigation was conducted using approved quality management procedures.
3. All identified corrective and preventive actions have been implemented or are subject to documented follow-up.
4. The company will continue enhanced post-market surveillance for the period defined in the Risk Management Plan.
5. Any significant new safety information will be reported to NAFDAC in accordance with applicable regulatory requirements.

12.13 REQUEST FOR REGULATORY CLOSURE

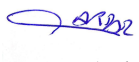
Afrimedical Manufacturing and Supplies Limited respectfully requests that NAFDAC review the enclosed documentation and consider the observations related to the Field Safety Notice and Field Safety Corrective Action to have been satisfactorily addressed.

We remain available to provide any additional information, clarification, or supporting evidence that the Agency may require during its final assessment.

12.14 DOSSIER INDEX

section	Title
section 1	Executive Response to NAFDAC
section 2	Investigation Report
section 3	Root Cause Analysis
section 4	CAPA Programme
section 5	Recall Strategy and Implementation
section 6	Revised Field Safety Notice (FSN)
section 7	ISO 14971 Risk Management File
section 8	Health Hazard Evaluation
section 9	QMS Enhancement Report
section 10	Technical Evidence and Manufacturing Review
section 11	Regulatory Annexes and Controlled Forms
section 12	Executive Regulatory Close-Out Report

12.15 EXECUTIVE APPROVALS

Name	Position	Signature	Date
Gabi Al Aridi	General Manager		27-07-2026
Emerenini Kingsley	Quality Assurance Manager		27-07-2026
Olayinka Sulaiman	Regulatory Affairs Manager		27-07-2026
George Alassad	Production/ Factory Manager		27-07-2026

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Egbe Daniella	Marketing Manager		27-07-2026
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FINAL STATEMENT

Afrimedical Manufacturing and Supplies Limited appreciates the guidance provided by the National Agency for Food and Drug Administration and Control during its review of the Field Safety Notice. The recommendations have been used to strengthen the company's quality systems, post-market surveillance processes, risk management practices, and regulatory documentation.

Through the implementation of the actions described in this twelve-section dossier, Afrimedical has demonstrated a structured, evidence-based approach to addressing the identified concerns while maintaining its commitment to patient safety, product quality, and continual improvement.

The company respectfully submits this dossier for regulatory review and remains committed to continued collaboration with NAFDAC in support of the safe supply of quality medical devices in Nigeria