INDEX NO: **391840**

NAFDAC REG NO: **A3-101445**

CERT NO: **A3-101445**

PRODUCT PIN NO:

APPLICANT TIN NO: **19739873-0001**

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Certificate of Registration

is hereby granted in respect of

Product
VITALS360 HEALTH MONITORING DEVICE

Name & Address of Company/Applicant
AKOSA HEALTH LIMITED

31, AKAOLISA STREET, URUAGU-NNEWI, NNEWI ANAMBRA STATE

Name & Address of Manufacturer
XIAMME LINKTOP TECHNOLOGY LTD

ROOM 2402A,DONGJIA BUILDING,JIABIANG ROAD LUOHU DISTRIC SHENZHEN, CHINA

This Certificate expires on **29 April, 2030**

Approval Date: **30 April, 2025**

Director - General
NAFDAC

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SCHEDULE TO CERTIFICATE OF REGISTRATION

NAFDAC REGISTRATION NO: **A3-101445**

1. Product Details

a	*Brand Name*	Vitals360 Health Monitoring Device
b	*Presentation*	360 UNITS
c	*Dosage Form/Strength*	
d	*Approved Pack Sizes*	250g
e	*Product HS Codes/Class No*	9006300000
f	*Safety Codes*	

2. Active Ingredients / Excipients

VITALS360

3. Medical Items

S/N	*Medical Item Name*	*Description*	*Presentation*	*Class Of Device*	*Pack Size*	*Unit of Measurement*	*Pack Type*	*Package Description*	*Number of Requested Unit*

Director - General
NAFDAC

TERMS OF USE OF NAFDAC CERTIFICATE OF PRODUCT REGISTRATION

1. The Certificate Holder must comply with all applicable laws, regulations, and guidelines governing the product's manufacture, importation, exportation, distribution, sale and advertisement.

2. The Certificate Holder must ensure that the product consistently meets safety, efficacy, quality and performance standards as prescribed by the Agency as well as relevant International Regulatory Bodies throughout its lifecycle.
3. The Certificate Holder must ensure that all packaging, and advertising materials consistently align with the approved information at the point of registration and all regulatory guidelines.
4. The Certificate Holder must obtain an advert approval from NAFDAC before the product is advertised on any media.
5. The Certificate Holder must obtain approval from NAFDAC before any variation/change in the product's composition, manufacturing process, labelling, packaging, or intended use is implemented.
6. The Certificate Holder must implement a robust pharmacovigilance system to monitor product safety and promptly report adverse events or quality defects to NAFDAC.
7. The Certificate Holder must maintain comprehensive records of importation, exportation, manufacturing, quality control, distribution, and complaints as well as allow regulatory inspection of such records, manufacturing sites and processes as may be required by NAFDAC.
8. The Certificate Holder must submit periodic safety update reports and renew the marketing authorisation as required by NAFDAC.
9. The Certificate Holder is advised to commence renewal of product registration six months before expiration of the product certificate
10. The Certificate Holder must have a system in place for product recalls and corrective actions in the event of non-compliance or safety issues.
11. The NAFDAC Registration Number on a NAFDAC Registration Certificate is unique to the product as approved and not transferable to another product.

12. The Certificate Holder must notify NAFDAC in advance of any decision to discontinue the manufacture, importation, exportation or distribution of the registered product.
13. NAFDAC reserves the right to suspend or cancel the Certificate of Product Registration if any of the conditions upon which the license was issued no longer exists.

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