THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR DUKE HCG PREGNANCY TEST STRIP

Version number 2.0, 25.05.2025

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1. Introduction

DUKE is a class B in-vitro diagnostic device belonging to the Immunology specialty category. It is approved in Tanzania as a kit for use in adult women of reproductive age.

1.1. Administrative Information

Registration number	TAN 25 MDR 0226
Brand Name (if relevant)	DUKE
Common name	HCG Pregnancy Test Strip
Class of the device and rule applied	Class B as per rule 4 of classification of in vitro diagnostic devices.
GMDN code and term	66852 Total Human Chorionic Gonadotropin IVD, Kit, Rapid ICT, Self-Testing
Name and complete address of the Market Authorization Holder	Matrix Exim (IND), 3750/2E/19, 3rd Floor, New Santa Fateh, Singh Nagar, Dugri Road, Ludhiana (Punjab) 141 002, India. E-mail: mandeep@matrixexim.com
Name and address(es) of local responsible person (LRP).	Orthorehab Tanzania Limited 4th Floor-HF 4/No. 1 -6, Sophia House, Chang'ombe Road, Chang'ombe, Dar es Salaam, Tanzania. dinesh.ortz@gmail.com

1.2. Assessment Procedure

The application for registration of DUKE was submitted on 21.02.2025. The product underwent full assessment. Assessment was completed in one (01) rounds of evaluation. DUKE was registered on 21.10.2025.

2. Technical information

2.1. Intended use

The intended use of DUKE as declared by the manufacturer and approved by TMDA is for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. DUKE is approved for use as a self-test for women of reproductive age.

2.2. Device details and features

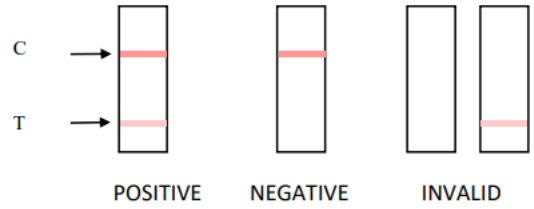
DUKE has been registered as a single invitro diagnostic device.

It is used to aid in the early detection of pregnancy. DUKE operates by utilizing antibodies including a monoclonal HCG-β antibody and goat anti-rat IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG-α monoclonal antibody as a mark tracer using the principle of double antibody sandwich method and gold immunochromatography assay. The test out-put is qualitative.

The type of specimen used is first morning urine/mid-stream urine and is collected by urinating in a clean, dry container.

Main Components
Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with HCG-α monoclonal antibody, nitrocellulose membrane coated with HCG-β monoclonal antibody control line coated with goat anti-rat IgG

Result Judgment



POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red bands appear or control line fails to appear. indicating that the operator error or reagent failure.

Reference value

The human chorionic gonadotrophin rapid test kit has a sensitivity of 25 mIU/mL. **Interpretation of Results**

1.The reagent only can be used for screening tests, just like all qualitative detection reagents.

2. If pregnancy is still suspected, a first morning urine specimen should be collected 24 to 72 hours later and tested

2.3. Commercial presentation

There are six (06) approved commercial presentations as follows: 1 test strip in a pouch as primary package. 01 test strip in a box, 20 test strips in a box, 40 test strips in a box, 50 test strips in a box and 100 test strips in a box as secondary package.

Additional contents include

Instruction for use

2.4. Items required but not submitted

Timer (It can be a clock or watch) and Disposable pipette tips, urine container.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions are to be stored as packed in the sealed pouch at 4-30°C, avoid heat and sunshine, dry place and do not freeze.

3.1.3. Shipping conditions

The recommended shipping conditions of 40°C to -20°C and 90% humidity is declared by manufacturer.

4. Manufacturing site audit

The manufacturer of the device is Qingdao Hightop Biotech Co., LTD, No. 369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, Shandong, 266112, China

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at The Affiliated Hospital of Qingdao University, No. 16 Jiangsu Road, Shinan District, Qingdao, Shandong Province, China. The following parameters were tested sensitivity and specificity.

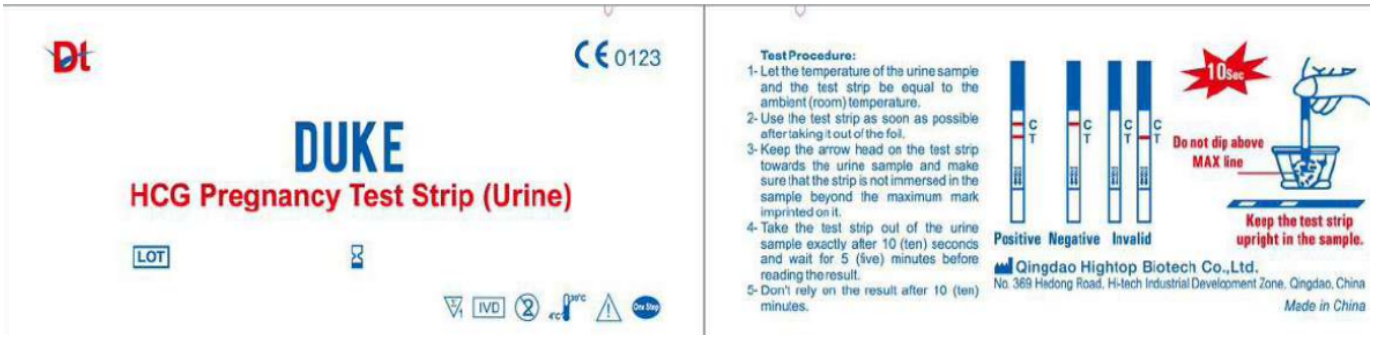
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that DUKE is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The instructions for use include all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack





6.3 Instructions for use/Package insert

See on the last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. DUKE is recommended for registration.

8. Post-approval updates

8.1 Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
None	None	None	None	None

8.2 Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
None reported	None reported	None reported

8.3 Re-registration applications

Not applicable.