THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR MEDI TEST HCG URINE PREGNANCY TEST

Version number 2.0, 25.05.2026

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.og.tz, Website: **www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

Medi Test is a class B in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a single invitro diagnostic device for use in female population of any age by healthcare professionals

1.1. Administrative Information

Registration number	TAN 25 MDR 0124
Brand Name (if relevant)	Medi Test
Common name	HCG Urine Pregnancy Test
Class of the device and rule applied	Class B, Rule 6 of in vitro diagnostic devices classification.
GMDN code and term	33819, Total human chorionic gonadotropin IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Medihyim Group Limited (97979) P.O. Box 72880, Magomeni Mwembechai 0733485027 Tanzania
Name and address(es) of local responsible person (LRP).	Medihyim Group Limited (97979) P.O. Box 72880, Magomeni Mwembechai 0733485027 Tanzania

1.2. Assessment Procedure

The application for registration of Medi Test was submitted on 14.02.2025. The product underwent full assessment. Assessment was completed in two rounds of evaluation. Medi test was registered on 12.06.2025.

2. Technical information

2.1. Intended use

The intended use of Medi Test as declared by the manufacturer and approved by TMDA is qualitative detection of hCG (human chorionic gonadotrophin) in urine to aid in the early diagnosis of pregnancy. Medi test is approved for use in healthcare settings by trained professionals only.

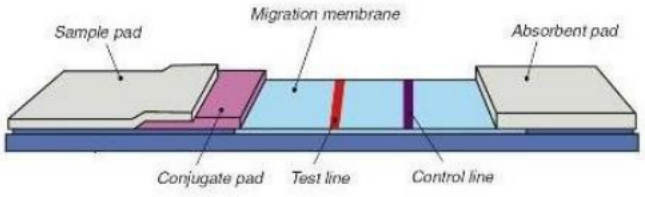
2.2. Device details and features

Medi test has been registered as a kit which consists of test strips and product insert.

Medi Test is a rapid test device. It is used to aid diagnosis of pregnancy. Medi test operates by Immuno-chromatography, a two-site immunoassay on a membrane. As the test sample flows through the membrane assembly of the dipstick, the colored anti-hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-hCG antibody coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any along with rabbit IgG colloidal gold conjugate move further on the membrane and are subsequently immobilized by the anti-rabbit IgG antibodies coated on the membrane at the control region, forming a colored band. This control band serves as an internal control to validate the test results. The test out-put is qualitative.

The type of specimen used is first morning urine and is collected by urinating in a clean and dry container.

Pregnancy Test (Strip /Dipstick) is an immuno-chromatographic assay. Each pouch contains a test strip. The test strip is composed of followings.



A. Sample pad: It is area of test strip where sample / specimen is applied. Sample pad is made of glass fibre sheet having buffering salts, biological detergents and preservative.

B. Conjugate pad: Conjugate pad is made of glass fibre sheet / special grade of paper having colloidal gold conjugated with monoclonal anti HCG & Rabbit IgG, buffering salts, biological detergents and preservative.

C. Nitrocellulose membrane: Nitrocellulose membrane is immobilised / coated with anti HCG in form of line at Test line region (T) and Goat anti rabbit IgG at control line region (C).

D. Absorbent pad: It made of cellulose paper and it absorbs the applied sample / specimen.

2.3. Commercial presentation

There is one approved commercial presentation as follows: one test strip/dipstick in an aluminum foil pouch as the primary package. 50 aluminium pouches are placed in hard cardboard box as the secondary package.

Additional contents include a desiccant and package insert.

2.4. Items required but not submitted

Specimen collection container and Timer.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 36 months.

3.1.2. Storage conditions

The recommended storage conditions is 2-30 ºC

3.1.3. Shipping conditions

The recommended shipping conditions is 2 to 45°C and 80% humidity.

4. Manufacturing site audit

The manufacturer of the device is Oscar Medicare Pvt. Ltd, E-92, Bahadrabad Industrial Area, Haridwar- 249402, Uttarakhand, 011-41076195/96, India.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: minimum detection limit, reproducibility, analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at DGChem Labs Pvt. Ltd, 231, U.S Complex, Adjoining Jasola Metro Station, Opp, Apollo Hospital, Mathura Road, New Delhi- 110076. 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 Medi test 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

<Paste the instructions for use>

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. Medi test 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