TMDA/DMD/MDA/F/014
Rev #:00

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR ANYTIME MALE LUBRICATED LATEX CONDOMS

Version number 2.0, 25.05.2026

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1. Introduction

Anytime is a class C medical device belonging to the dual contraception specialty category. It is approved in Tanzania as a single device for use in male adults and elderly by general public.

1.1. Administrative Information

Registration number	TAN 24 MDR 0154
Brand Name (if relevant)	Anytime
Common name	Male lubricated Latex Condom
Class of the device and rule applied	C according to rule 16 of medical devices classification
GMDN code and term	45138, Basic male condom, Hevea-latex.
Name and complete address of the Market Authorization Holder	Indus Medicare Private Limited, Suryodaya, 1-10-60/3, Begumpet, Hyderabad, Telangana – 500 0016, India
Name and address(es) of local responsible person (LRP).	Tansoko Agrovet Limited, Block 10, Uhuru Street, Ilala Uhuru/Bungoni, P.O. Box 22581, Dar es salaam, Tanzania.

1.2. Assessment Procedure

The application for registration of anytime was submitted on 31.05.2024. The product underwent full assessment. Assessment was completed in 1 round of evaluation. Anytime was registered on 29.08.2024.

2. Technical information

2.1. Intended use

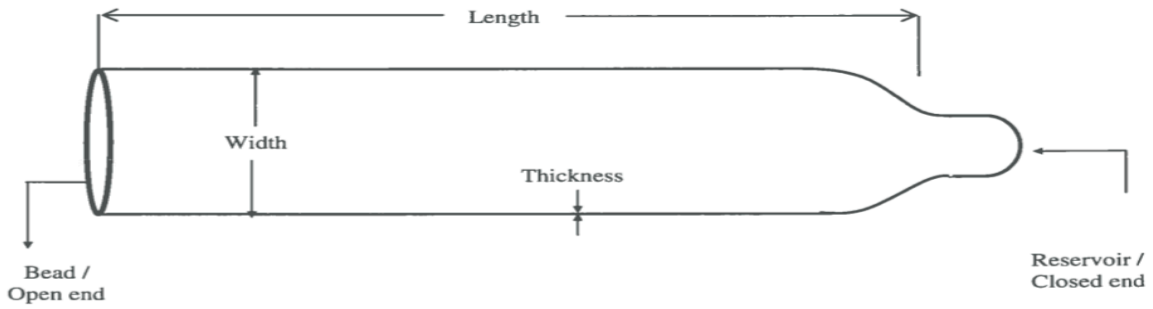
The intended use of anytime as declared by the manufacturer and approved by TMDA is intended to be retained on the penis during sexual activity, for the purposes of contraception and prevention of Sexually Transmitted Infections (STI's). Anytime is approved for use in general public by male adult and elderly.

2.2. Device details and features

Anytime has been registered as a single medical device.

Anytime contraception and prevention of transmission of sexually transmitted infections (STI). Anytime condoms are made from natural rubber latex which is manufactured by vulcanization process allowing the condom to be elastic and flexible that can be molded easily into different shapes. The elastic physical barrier maximizes its ability to prevent transmission of sexually transmitted infections and preventing access of sperms to the female reproductive system.

Non spermicidal lubricant is added to allow sexual intercourse without discomfort, pain or tissue damage for both partners, facilitating the unrolling of the condom during donning and reducing the risk of damage to the condom itself.



Product Description	:	Plain Reservoir End Condom		
Dimensions	:	**Length (mm)**	**Width (mm)**	**Thickness (mm)**
		Min. 180	53 ± 2	0.065 ± 0.010 (Normal) - W H O 0.070 ± 0.010 (Normal) - IS/ISO 4074

2.3. Commercial presentation

There are two approved commercial presentations as follows: 1 condom in foil pouch as primary package ;144 condoms and 100 condoms in a box as secondary pack.

2.4. Items required but not submitted

No any other item required

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 60 months.

3.1.2. Storage conditions

The recommended storage conditions are cool and dry place, temperature below 35^{o}C

3.1.3. Shipping conditions

The recommended shipping conditions is 0^{o}C-35^{o}C

4. Manufacturing site audit

The manufacturer of the device is Indus Medicare Private Limited – Ramaipally (V), Medak District, 502336 Telangana, India.

Quality audit of the manufacturing facility was conducted through site visit on 30th September - 01st October, 2024. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

Not applicable

Clinical evidence

Clinical evaluation was conducted at Ramaipally (Village), Medak District, Telangana – 502 336, India. The following parameters were verified: Compliance with Specific Standards, Pre-clinical Testing, Clinical Studies, Scientific Literature Reviews, and Post-Market Surveillance (PMS) and the clinical study demonstrates that the natural rubber latex condom is a highly safe, reliable, and acceptable device for contraception and STI prevention.

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





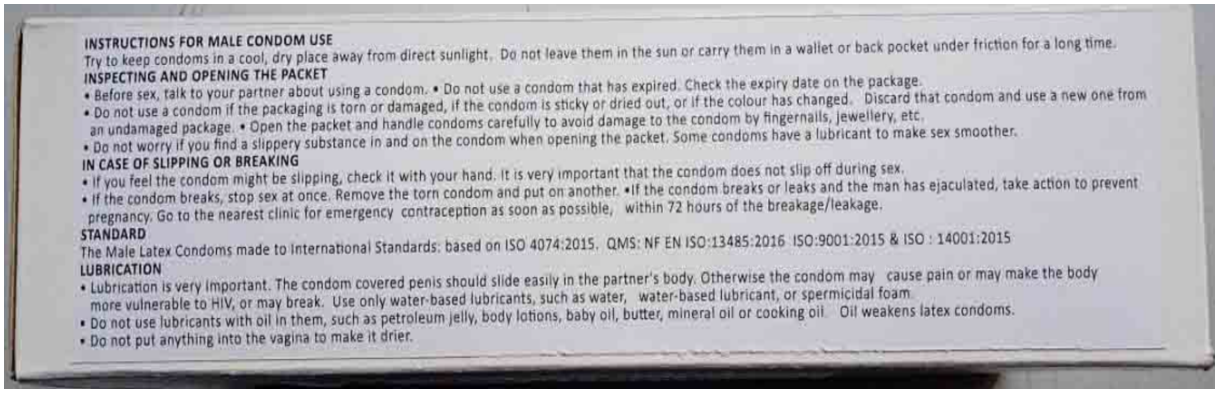
6.2. Secondary pack




Anytime™
feel safe
Premium Quality
Male Lubricated
Latex Condoms
100 % electronically tested


Indus Medicare Private Limited,
Regd.office: Suryodaya, 1-10-60/3,
Begumpet, Hyderabad 500 016.
Factory: Ramaipally(V), Medak Dist.-502336
Telangana, India. Mfg.Lic.No.:MFG/MD/2023/000293)
www.indusmedicare.com


LOT
2402060
2029-01
CE 0459
Nominal width: 53mm
LATEX



INSTRUCTIONS FOR MALE CONDOM USE

Try to keep condoms in a cool, dry place away from direct sunlight. Do not leave them in the sun or carry them in a wallet or back pocket under friction for a long time.

INSPECTING AND OPENING THE PACKET

- Before sex, talk to your partner about using a condom. • Do not use a condom that has expired. Check the expiry date on the package.
- Do not use a condom if the packaging is torn or damaged, if the condom is sticky or dried out, or if the colour has changed. Discard that condom and use a new one from an undamaged package. • Open the packet and handle condoms carefully to avoid damage to the condom by fingernails, jewellery, etc.
- Do not worry if you find a slippery substance in and on the condom when opening the packet. Some condoms have a lubricant to make sex smoother.

IN CASE OF SLIPPING OR BREAKING

- If you feel the condom might be slipping, check it with your hand. It is very important that the condom does not slip off during sex.
- If the condom breaks, stop sex at once. Remove the torn condom and put on another. •If the condom breaks or leaks and the man has ejaculated, take action to prevent pregnancy. Go to the nearest clinic for emergency contraception as soon as possible, within 72 hours of the breakage/leakage.

STANDARD

The Male Latex Condoms made to International Standards: based on ISO 4074:2015. QMS: NF EN ISO:13485:2016 ISO:9001:2015 & ISO : 14001:2015

LUBRICATION

- Lubrication is very important. The condom covered penis should slide easily in the partner's body. Otherwise the condom may cause pain or may make the body more vulnerable to HIV, or may break. Use only water-based lubricants, such as water, water-based lubricant, or spermicidal foam.
- Do not use lubricants with oil in them, such as petroleum jelly, body lotions, baby oil, butter, mineral oil or cooking oil. Oil weakens latex condoms.
- Do not put anything into the vagina to make it drier.

Mock up label for carton box label

LOT NUMBER	LOT	**: 2402060**
EXPIRY DATE		**: 2029-01**
Nominal width of condoms		**: 53MM**
TYPE		**: Male Lubricated Latex Condoms**
Brand		**: Anytime - 100's**
QTE. / QTY.		**: 4,000 PIECES**
NET WT.		**:**
GROSS WT.		**:**
MADE IN INDIA		
Dimensions		**: 585 x 345 x 475 mm**

Anytime Condoms

Manufactured by .: INDUS MEDICARE PRIVATE LIMITED
Regd. Office : 1-10-60/3, Begumpet, Hyderabad 500 016, Telangana, India.
Factory : Ramaipally(V), Medak Dist.-502336 Telangana, India.
(Mfg.Lic.No. : MFG/MD/2023/000293)
www.indusmedicare.com

STORE IN WELL-VENTILATED AND DRY STORAGE CONDITIONS, AWAY FROM DIRECT SOURCES OF HEAT, INCLUDING SUNLIGHT.

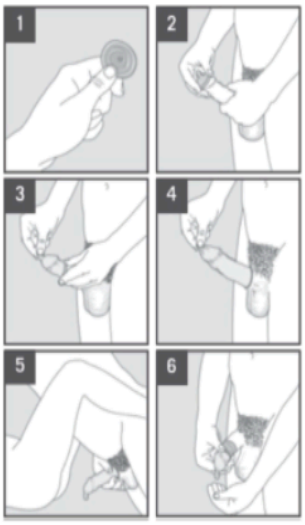


HANDLE WITH CARE

6.3 Instructions for use/Package insert

INSTRUCTIONS FOR MALE CONDOM USE

When used correctly every time you have sex condoms greatly reduce the risk of unintended pregnancy, HIV/ AIDS and some other sexually transmitted infections. Use a new condom every time you have sex and follow the Instructions carefully.



BEFORE INTERCOURSE

1. Carefully open the package so the condom does not tear. Do not unroll the condom before putting it on.
2. If you are not circumcised, pull back the foreskin. Put the condom on the end of the hard penis.
   Note: If the condom is initially placed on the penis backwards, do not turn it around.
   Throw it away and start with a new one.
3. Pinching the tip of the condom to squeeze out air, roll on the condom until it reaches the base of the penis. Place the condom on the erect penis before any contact occurs between the penis and the partner's body to assist in the prevention of sexually transmitted infections and pregnancy.
4. Check to make sure there is space at the tip and that the condom is not broken. With the condom on, insert the penis for intercourse.

AFTER INTERCOURSE

5. When withdrawing the penis after sex and soon after ejaculation, hold the rim of the condom to keep the condom in place.
6. Remove the condom while the penis is still hard. Be careful not to spill any semen on the woman's genitals.

DISPOSAL OF THE CONDOM: Wrap the used condom in a piece of paper and throw it away safely where children cannot get hold of it. Dispose in a closed rubbish bin, burry or burn. It may be disposed by throwing in a pit latrine. Do not throw it in a flushing toilet.
WARNING! Use the condom only once. Do not re-use the Condom. Re-use of Condom may result breakage and may increase incidents of pregnancies and diseases. The Condom is made from Natural Rubber Latex which might cause Allergic Reactions including Anaphylactic Shock, if the user is Allergic to Latex. Consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom.

Explanation of ISO 15223-1, Version 2021, (Medical device symbols to be used with information, supplied by the Manufacturer Part 1).



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. Anytime is recommended for registration.

8. Post-approval updates

8.1 Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
TMDA0024/MDR/0136/A1	10.09.2024	To add pack of 144 along with currently registered pack of 100	08.10.2024	08.10.2024

8.2 Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3 Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date