1. Identification of the medical device and its Manufacturer

PRODUCT NAME:
Dallop® NM, Dallop® NM ULTRALIGHT
Urological tape for surgical treatment of urinary incontinence

CLASS:
Class III medical device in accordance with rule 8 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (all implantable devices and surgical invasive devices for long-term use).
Product classification specified in the declaration of conformity, which constitutes Annex DT 018.Z1 to the technical documentation.

BASIC UDI-DI CODE: 59061465FFKXXXXXF

PRODUCT LIST:

PRODUCT LIST OF Dallop® NM, Dallop® NM ULTRALIGHT			
NO	**PRODUCT NAME**	**SIZE**	**INDEX**
1	Dallop® NM ULTRALIGHT	30 cm	MB-271-TNMU-001
2	Dallop® NM ULTRALIGHT	45 cm	MB-271-TNMU-002
3	Dallop® NM	45 cm	MB-271-TNMS-004
4	Dallop® NM	60 cm	MB-271-TNMS-003

MANUFACTURER: TRICOMED S.A.

ADDRESS OF THE MANUFACTURER: ul. Świętojańska 5/9, 93-493, Łódź, Polska

REGISTRATION NUMBER IN THE EUDAMED DATABASE: PL-MF-000002483

NAME AND NUMBER OF THE NOTIFIED BODY:
Polish Centre for Testing and Certification S.A. 1434
ul. Puławska 469
02-844 Warsaw, Poland

2. Intended use of the medical device, indications, contraindications and target population

INDICATIONS:
Dallop® NM and Dallop NM® ULTRALIGHT urological tapes are recommended for use during the surgical traetment of Stress Urinary Incontinence (SUI). Surgical treatment of urinary incontinence involves the sunspension of the urethra using tension-free urological tape. The devices are intended for implantation using the following methods: Tension free Vaginal Tape (TVT), Trans Obturator Tape (TOT) or Tension free Vaginal Tape-Obturator (TVT-O). The surgeon chooses the optimal method. Specially designed applicators, depending on the chosen method, allow for safe instertion of the urological tape into the patient's body.

The products are intended for use by professional user – a specialist doctor, in female patients classified for the surgical treatment of Stress Urinary Incontinience.

CONTRAINDICATIONS:

Dallop® NM, Dallop® NM ULTRALIGHT medical devices should not be used:

- in female patients allergic to polypropylene,
- in women planning pregnancy and pregnant women,
- in children and where the physiological growth proces limited their use,
- in female patients with coagulation disorders, taking oral anticoagulants or other coagulation affecting medicaments (including acetylsalicylic acid),
- in female patients with urinary tract infection,
- in female patients undergoing urethal surgery at the same time.

TARGET USERS:

Professional users - surgeon implanting the device

Place of use of the product – hospitals, clinics (operating theatres)

TARGET PATIENT POPULATION:

Patients qualified for surgical treatment of urinary incontinence

3. General description of the product

Non-resorbable, surgical urological tapes are knitted of monofilament polypropylene yarn – transparent (Dallop® NM) and transparent and blue (Dallop® NM ULTRALIGHT). The Dallop® NM ULTRALIGHT product has a blue line along the product, which facilitates visibility in the operating field and enables its identification if tension improvment is needed. The products are equipped with blue handles made of polypropylene, monofilament yarn, secured with heat-shrinkable tubing, which facilitates fixation of the product on the applicator. The products do not contain any substances of allogenic or animal orgin. Pyrogen-free products.

Products composition: 100% polypropylene

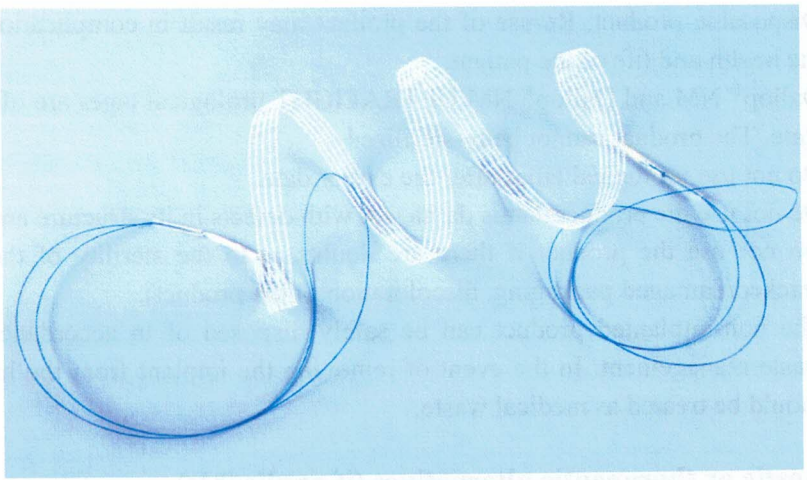
The Dallop® NM product has been present on the market and used by specialists for many years, so its continued use does not pose any significant risk. In 2017 the element securing the tape-handle connection in urological tapes (the heat-shrink tube) was modernized. The modernization was carried out in response to market feedback. The raw material used for that purpose was biologically tested in accordance with the requirements of ISO 10993 standards. The modernization introduced did not change the nature, purpose, safety or clinical effectiveness of the assessed product.

In order to increase the competitiveness of TRICOMED S.A. products in the field of urogynecological implants, the Dallop® NM ULTRALIGHT product was also created, characterized by low surface mass, with orientation lines facilitating its visibility in the surgical field.

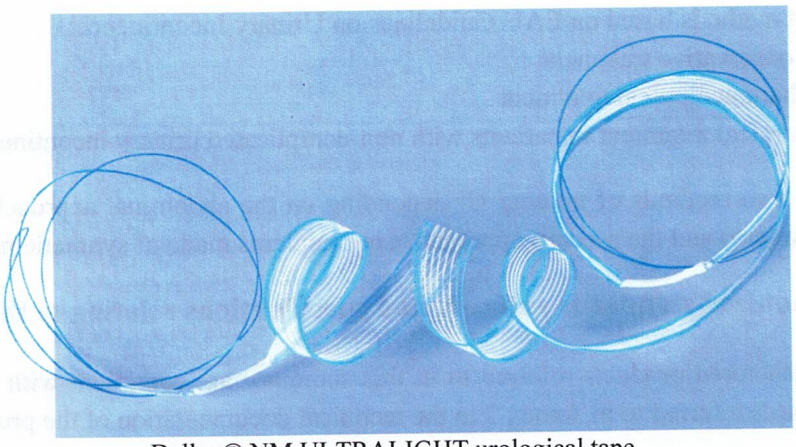
Based on reports from PMS (Post Market Surveillance) activities for Tricomed products, in 2020 the design of the Dallop® NM ULTRALIGHT implant was modernized - namely, the width of the tape was changed from 1.3 mm to 1.1 mm. The reasons for narrowing the device were doctors' opinions suggesting that the tape may be slightly too wide in the case of patients with a short urethra. The

modernization introduced did not change the nature, purpose, safety or clinical effectiveness of the assessed device.

Single-use product. Re-use of the product may result in complications or serious damage to the patient's health and life. Dallop® NM, Dallop® NM ULTRALIGHT urological tapes are offered for sale as a sterilized product in the sterilization process with ethylene oxide (EO).



Dallop® NM urological tape



Dallop® NM ULTRALIGHT urological tape

4. Information on any residual risk, adverse effects and precautions

SIDE EFFECTS:

The use of Dallop® NM or Dallop® NM ULTRALIGHT tape may cause the following complications: tearing out or tearing fixing the tape on the applicator, micturion disorders, de novo urgency, erosion of the vagina or the tape, haematomas, fever, recurrent stress urinary incontinence, signs of infection, postoperative pain, perforation of the bladder or urethea. The above-mentioned complications may contribute to prolonged treatment time, reoperation, and in rare cases the necessity of complete resection of the tape. The use of a non sterile, damaged device and its re-use may result in the above-mentioned complications or serious damage to the health and life of the patient. Any serious incydent related to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user or the patients resides.

SAFETY PRECAUTIONS:

1. The products are intended for use by qualified and properly trained medical personnel.
2. Urological tapes should be used only in conditions where strict surgical asepsis is possible. In order to ensure strict surgical asepsis during the procedure, it is advisable to apply special precautions (use of personal protection, sterilization of instruments, high personal hygiene) and extreme care during the preparing the site of direct intervention by the surgeon.
3. Urological tapes should only be used on non-infected wounds.
4. Disposable product. Re-use of the product may result in complications or serious damage to the health and life of the patient.
5. Dallop® NM and Dallop® NM ULTRALIGHT urological tapes are offered for sale in a sterile state. The product cannot be re-sterilized.
6. Do not use urological tapes after the expiry date.
7. Do not use the product that is damaged, with defects in its structure and dirty.
8. Do not use the product if there are doubts as to the sterility of the product (e.g. wetting, cracked/damaged packaging, discoloration of the product).
9. The non-implanted product can be safely disposed of in accordance with general rules of waste management. In the event of removing the implant from the human body, the product should be treated as medical waste.

5. Diagnostic or therapeutic alternatives (if applicable)

Treatment methods based on EAU Guidelines on Urinary Incontinence:

1. Conservative treatment
2. Pharmacological treatment
3. Surgical treatment in patients with non-complicated urinary incontinence

There are two methods of treating UI depending on the abdominal approach (open and laparoscopic tension surgery) and the modern approach using implants made of synthetic materials.

6. Harmonized standards and common specifications relating to the medical device

The manufactured products referred to in this summary are compliant with the reference documents and standards referred to in Annex 2 to the technical documentation of the products.

7. Summary of clinical evaluation and post-marketing clinical follow-up information

Based on the clinical assessment, it was concluded that the benefit/risk profile, undesirable effects and safety of use are consistent with a high level of health and safety protection and are acceptable in accordance with current knowledge and the state of technology. The benefits of using the medical device outweigh the existing risks. Information from the post-production phase is collected and analyzed on an ongoing basis. Moreover, the staff involved in risk management processes is suitably qualified and experienced.

In urological tapes subject to clinical evaluation the manufacturer does not plan to introduce changes in production procedures. Correct parameters and manufacturing conditions are both ensured and controlled.

Based on the evaluation of post-marketing clinical observations, it was determined that these devices are effectively and safely implanted by medical specialists. Dallop® NM and Dallop® NM

ULTRALIGHT products have not caused any medical incidents during the entire period of their presence on the market, and complications related to their use are standard for a given group of products.

8. Training and product user profile

The products are intended for use by qualified and properly trained medical personnel.

OPRACOWAŁ	ZATWIERDZIŁ
TRICOMED S.A. PEŁNOMOCNIK ZARZĄDU ds. Systemu Zarządzania Jakością, Bezpieczeństwa i Rejestracji Wyrobów mgr Paulina Nasiłowska Imię, nazwisko, podpis	TRICOMED S.A. PREZES ZARZĄDU dr hab. inż. Witold Sajkiewicz Imię, nazwisko, podpis