1. Identification of the medical device and its manufacturer

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

DEVICE CLASS:
Class III medical device pursuant to 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). The device classification is specified in the Declaration of Conformity, which is Attachment 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**	**PRODUCT CODE**
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.

MANUFACTURER'S ADDRESS: ul. Świętojańska 5/9, 93-493, Łódź, Polska

MANUFACTURER'S UNIQUE REGISTRATION NUMBER: PL-MF-000002483

NAME AND ADDRESS OF THE APPROPRIATE NOTIFIED BODY:
Polish Centre for Testing and Certification S.A. 1434
ul. Puławska 469
02-844 Warszawa

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

INTENDED USE:
Dallop® NM, Dallop® NM ULTRALIGHT urological tapes are recommended for use during surgical procedures for the treatment of Stress Urinary Incontinence (SUI). The surgical treatment of urinary incontinence involves suspending the urethra with a 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 choice of the optimal method is made by the physician. Specially designed applicators, depending on the chosen method,

allow for the safe introduction of the urological tape into the patient's body. The devices are intended for use by a professional user – a specialist physician – in patients qualified for surgical treatment of Stress Urinary Incontinence.

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

- in patients allergic to polypropylene,
- in women planning pregnancy and pregnant women,
- in children and where the physiological growth process limits their use,
- in patients with clotting disorders, who use oral anticoagulants or other drugs affecting clotting (including acetylsalicylic acid),
- in patients with urinary tract infection,
- in patients who are simultaneously undergoing urethral surgery.

TARGET USERS:
Patients suffering from stress urinary incontinence.

TARGET PATIENT POPULATION:
The population consists of patients suffering from stress urinary incontinence who have no contraindications for surgical treatment and no tendency for allergy to polypropylene.

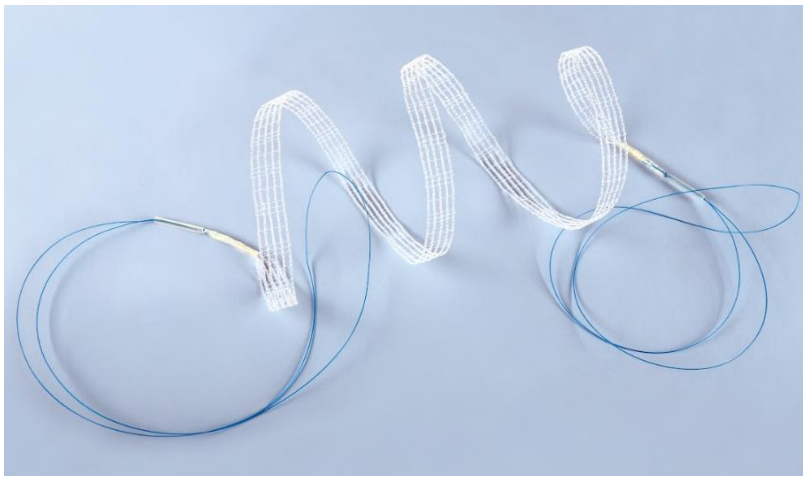
3. General product description

The non-absorbable, surgical urological tapes are manufactured using a knitting technique from monofilament polypropylene yarn, in transparent colour (Dallop® NM) and in transparent and blue colours (Dallop® NM ULTRALIGHT).
The Dallop® NM ULTRALIGHT device features a blue line along the product, which improves visibility in the surgical field and enables its identification if tension adjustment is necessary.
The devices are equipped with blue handles made of monofilament polypropylene yarn, secured with a heat-shrink tube which facilitates the device's attachment to the applicator.
The devices do not contain substances of allogeneic or animal origin. The devices are non-pyrogenic.
Device composition: 100% Polypropylene

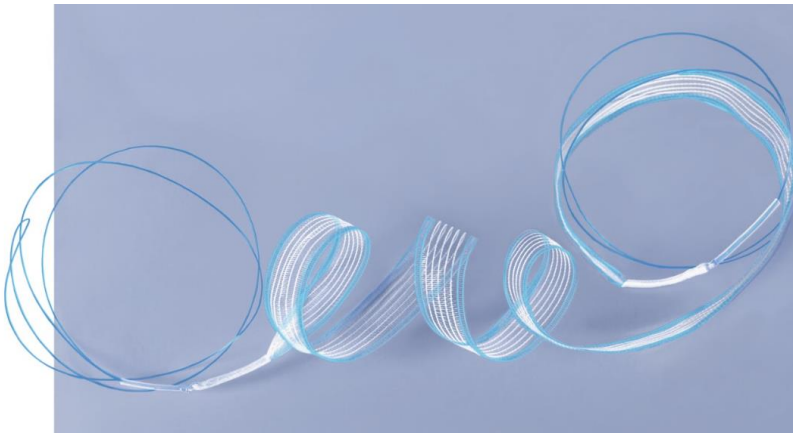
The Dallop® NM device has been on the market and used by specialists for many years, so its continued use does not involve significant risk. In 2017, the securing element for the tape-handle connection, i.e., the heat-shrink tube, was modernized in the urological tapes. The modernization was carried out in response to market feedback. A material with biological tests performed in accordance with the requirements of ISO 10993 standards was used. The implemented modernization did not affect the change in the nature, intended purpose, safety, or clinical efficacy of the device being evaluated.
To increase the competitiveness of TRICOMED S.A. products in the field of urogynaecological implants, the Dallop® NM ULTRALIGHT device was also created, characterized by a low surface mass, with orientation lines facilitating its visibility in the surgical field. Based on reports from Post Market Surveillance (PMS) activities for Tricomed products, the construction of the Dallop® NM ULTRALIGHT implant was modernized in 2020, specifically changing the tape width from 1.3 cm to

1.1 cm. The reason for narrowing the device was physicians' opinions suggesting that the tape might be slightly too wide in patients with a short urethra. The implemented modernization did not affect the change in the nature, intended purpose, safety, or clinical efficacy of the device being evaluated.

The device is for single use. Reusing the device may result in complications or serious harm to the patient's health and life. Dallop® NM, Dallop® NM ULTRALIGHT urological tapes are offered for sale as a sterilized product through the ethylene oxide (EO) sterilization process.



Dallop® NM urological tape



Dallop® NM ULTRALIGHT urological tape

4. Information on residual risks, adverse effects, and precautions

ADVERSE EFFECTS:

The use of Dallop® NM or Dallop® NM ULTRALIGHT tape may cause the following complications: tearing or breaking of the handles securing the tape to the applicator, urinary dysfunction, *de novo* urgency, vaginal or tape erosion, haematoma, fever, recurrent urinary incontinence, signs of infection, postoperative pain, bladder or urethral perforation. The listed complications may contribute to prolonged treatment time, subsequent surgical intervention, and in rare cases, the need for complete tape resection.

Use of a non-sterile, damaged, or reused device may result in the above-mentioned complications or serious harm to the patient's health and life.
Any serious incident related to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is resident.

PRECAUTIONS:
1. The devices are intended for use by qualified and properly trained medical personnel
2. Urological tapes should only be used in conditions where strict surgical asepsis can be maintained. To ensure strict surgical asepsis during the procedure, special precautions are indicated (use of personal protective equipment, sterilization of instruments, maintaining high personal hygiene) and extraordinary attention during the preparation of the area of direct surgical intervention.
3. Urological tapes should only be used in non-infected wounds..
4. The device is for single use. Reusing the device may result in complications or serious harm to the patient's health and life.
5. Dallop® NM, Dallop® NM ULTRALIGHT urological tapes are offered for sale in a sterile condition. The device must not be re-sterilized.
6. Do not use urological tapes after the expiry date.
7. Do not use a damaged, structurally defective, or contaminated device.
8. Do not use the device if there are doubts about the sterility of the device (e.g., wetness, cracked/damaged packaging, device discoloration).
9. An un-implanted device can be safely disposed of in accordance with general waste management rules. If the implant is removed from the human body, the device 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 for women with uncomplicated SUI

Two main types of SUI treatment can be distinguished: those involving abdominal access (open and laparoscopic, tension procedures) and the modern approach using implants made of synthetic materials.

6. Harmonised standards and common specifications applicable to the medical device

The manufactured devices referred to in this summary comply with the following harmonised standards: EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, EN ISO 10993-23:2021, EN ISO 11135:2014, EN ISO 10993-10:2023, , EN ISO 10993-18:2020, EN ISO 11607-1:2020, EN ISO 11607-1:2020/A1:2023, EN ISO 10993-9:2021, EN ISO 10993-12:2021, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 15223-1:2021.

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

Based on the clinical evaluation performed, it was found that the benefit/risk profile, adverse 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 state of the art.
The benefits of using the medical device outweigh the existing risks. Post-production information is continuously collected and analysed. Furthermore, the personnel involved in risk management processes are appropriately qualified and experienced.
The manufacturer does not plan to introduce changes to the production procedures for the urological tapes subject to the clinical evaluation. Correct parameters and manufacturing conditions are ensured and controlled.
Based on the evaluation of post-market clinical follow-up, it was found that these devices are effectively and safely implanted by specialist physicians. The Dallop® NM and Dallop® NM ULTRALIGHT devices have not caused medical incidents throughout their presence on the market, and complications associated with their use are standard for this device group.

8. Training and profile of device user

The devices are intended for use by qualified and appropriately trained medical personnel.

PREPARED BY:	APPROVED BY:
Name, Surname, Signature	Name, Surname, Signature