

## TMS MEDİKAL PLASTİK ÜRÜNLER SAN. VE DIŞ TİC. LTD. STİ.

İstanbul Deri OSB Mah. Alsancak Sk. No:3/A Tuzla - İSTANBUL Tel: 0216 504 18 67 E-mail: info@tmsmedikal.com Tuzla V.D.: 8450330385 - Tic. Sicil No: 972249-0 Mersis No: 0845033038500010

www.tmsmedikal.com

## **EU DECLERATION OF CONFIRMITY**

## According to Regulation (EU) 2017/745

- 1. Manufacturer information:
  - 1.1 Name: TMS MEDIKAL PLAST. URUN. SAN. VE DIS TIC. LTD. STI.
  - 1.2 Address: Istanbul Deri Osb. Mah. Alsancak Sok. No: 3/A Tuzla / Istanbul
- 2. The undersigned states that this EU decleration of confirmity is issued under responsibility of TMS MEDIKAL.
- 3. Basic UDI-DI: 869886383T201791QT
- 4. Product information:
  - 4.1 Product trade name and product code: Vaginal Speculum

REF CODE & MODEL
T201791 SMALL
T201792 MEDIUM
T201793 LARGE

- 4.2 Intended Purpose: A vaginal speculum is a medical device that allows physicians and health providers to better view a woman's cervix and vagina during pelvic exams.
- 5. Product risk class according to annex VIII, rule 1: class I sterile.
- 6. TMS MEDIKAL is registered in EUDAMED with actor code TR-MF-000019237
- 7. The undersigned declares that the products referred to in this statement are covered by the present decleration and they are in confirmity with Regulation (EU) 2017/745.

Place: Tuzla / Istanbul TURKEY

Date 30.05.2022

Name: Tarık Alp Sarı

Function: General Manager

TMS MEDIKAL PLASTIK ÜRÜNLER SAN DISTE LID. STI. İstanbur Daveriganize Sanayi Bölgesi Jó-6 Nolu Parsel Als<del>ancak Sək No. 3N</del> Kat 1 Tuzla-İstanbul-TÜRKEY Tuzla V.D. 845 0330 385