



## DECLARATION OF CONFORMITY

We

Manufacturer: **"ELASTIKUM" Limited Liability Company**  
Address: building No.28, Yangikurgon-2 street, "Yoshlik" mahalla citizens gathering,  
Parkent district, Tashkent region, 111305, Republic of Uzbekistan

declare under sole responsibility for issuing this declaration of conformity in relation to the following medical devices:

**Medical bleached cloth gauze non-sterile in rolls 90 cm x 100 m, m, 90 cm x 1000 m, m, 90 cm x 200 m, 90 cm x 400 m, and in pieces 90 cm x 1 m, 90 cm x 2 m, 90 cm x 3 m, 90 cm x 5 m, 90 cm x 10 m, 90 cm x 25 m and medical gauze bandages 5 m x 10 cm, 7 m x 14 cm.**

**Basic UDI-DI:** 478001914TDoc-0016W

For the above given medical devices in hereby declared that it conforms to the essential requirements set out in community legislation mentioned below:

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices**

Statement about the relevant harmonized standarts that have been used in relation to which conformity is declared:

**EN 14079:2003, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018**

Medical devices classification (according to the Annex VIII to the Regulation (EU) 2017/745 & ED N 93/42/EEC)

**Class I, rule 4**

**The conformity Assessment Route** of medical devices has been selected according to the Annex IX to the Regulation (EU) 2017/745

Our European Authorized Representative: **BARAMED S.R.L.**  
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**Signed for and behalf of:**

Republic of Uzbekistan, Tashkent city  
(place of issue)

June 22, 2023  
(date of issue)

