



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 non – sterile 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 standards 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.

Legal address; The Republic of Moldova

Chisinau. st. Cuza Voda.1/2, office 109

Tel: +37369230364, E mail: svictor444@yahoo.com

Signed for and behalf of:

Republic of Uzbekistan, Tashkent city
(place of issue)

June 22, 2023
(date of issue)

