

DECLARATION OF CONFORMITY

WITH CE REQUIREMENTS

(Accordingly European Directive No. 93/42/EEC)

Limited Liability Company "TF MEDTEKS"
601337 Russia, Vladimirskaya reg.,
Kameshrovskiy distr., pos.im.K.Marksa, Shosseynaya str. 11
Tel. +74924857187, e-mail: medtex2010@mail.ru

Declares that the describes product is in conformity with the applicable provisions of Annex I, Essential Requirements of Council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC:

NON-STERILE MEDICAL GAUZE MADE OF ABSORBENT COTTON

Class I

The product conformity is assessed against the requirements of Annex VII of the Directive 93/42 EEC by LLC "TF MEDTEKS".

The product carries **CE** mark accordingly.

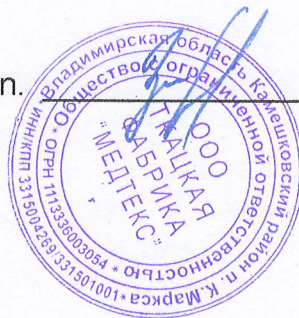
Harmonized standards applied:

- EN ISO 13485:2016
- EN ISO 14079:2010

LLC "TF MEDTEKS" has implemented and certified a Medical Devices Quality Management System accordingly EN ISO 13485:2016 (certificate No. СДС.ФР.СМ.00412.19) by an notified body from Russia (Federal Register)address: of. 515,516, building 5 lit. E, Griboedov canal emb., 191186, Saint-Petersburg, Russia

LLC "TF MEDTEKS"

sign.



/Oleg Zakharov/
General Director
Date: 05/08/2019