

Declaration of conformity

GEXA MEDOD Medical face mask, non-sterile, Type I

Basic UDI-DI: 4607050210258647V

Product identification number: TS 9398-017-18603495-2010

Authorised Representative: Cityw Europe OÜ, reg.14569583, Pärnu mnt. 10, 10148, Tallinn, Estonia

Manufacturer: LLC Gexa – nonwoven materials, 3,A,A1,A2,a, r.304, Tsentralnaya str., Goljovo, Krasnogorsk, Moscow region, Russia, 143405

Intended purpose: to protect the patient from infective agents. Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Declaration of conformity is issued to the manufacturer's sole responsibility, and herewith we confirm that the named medical product meets the essential requirements, set by the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, and also by the Medical Devices Act of Estonia and legislation established on the basis thereof.

The medical device is classified as risk Class I device, in accordance with the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, Annex VIII, Classification Rules, Non-invasive Devices; Rule 1, as: "All non-invasive devices are classified as Class I, unless one of the rules set out hereinafter applies".

EU declaration of conformity issued after drawing up the technical documentation set out in Annexes II and III of the REGULATION (EU) 2017/745.

The medical device complies with the applicable clauses of the following international standards:

- harmonized standard EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods;
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;
- ISO 10993 Biological evaluation of medical devices – Parts 2, 5, 9, 10 and 11

Declaration of conformity has been first issued and CE-mark applied on 05.03.2021.

Krasnogorsk, December 8th, 2021

Bunin A.F.
General Director

LLC Gexa – nonwoven materials

