

Declaration of conformity

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

Basic UDI-DI: 46070502125864HB

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 use: intended for use in hospitals and other medical settings in order to limit the transmission of infective agents from staff to patients. The masks may also be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situation.

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.

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 08.12.2021.

Krasnogorsk, December 23th, 2021

Bunin A.F.

General Director

LLC Gexa – nonwoven materials

