

EU declaration of conformity

Disposable gown, non-sterile, made from nonwoven material Spunbond

1. GEXA MEDOD Gown

Product identification number: TS 9398 – 020 – 18603495 – 2009

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

Declaration of conformity is issued to the manufacturer's sole responsibility, and herewith we confirm that the named products meet the applicable essential health and safety requirements, set by the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment.

The device is classified as risk Category I, in accordance with the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment, Annex I, Risk categories of PPE.

The device is in conformity with the applicable clauses of the harmonized international standard:

- EN ISO 13688:2013 Protective clothing — General requirements (ISO 13688:2013)
- ISO 13688:2013/AMD 1:2021 Protective clothing — General requirements — Amendment 1

and the applicable clauses of the international standards:

- 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 8th, 2021

Bunin A.F.

General Director

LLC Gexa – nonwoven materials

