GEXA
nonwoven materials

Declaration of conformity

Disposable medical linen, non-sterile, made from nonwoven material Tutami adsorb S

1. **GEXA MEDBEL Medical Sheet, Tutami adsorb S.**
   Basic UDI-DI: 4607050210259167P
2. **GEXA MEDBEL Medical Sheets in roll, Tutami adsorb S.**
   Basic UDI-DI: 4607050210259237L
3. **GEXA MEDBEL Medical Napkin, Tutami adsorb S.**
   Basic UDI-DI: 4607050210259377X
4. **GEXA MEDBEL Medical Napkins in roll, Tutami adsorb S.**
   Basic UDI-DI: 4607050210259307H

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

Intended purpose: for use in inpatient and outpatient medical centers, healthcare and social service facilities to prevent the spread of infectious agents between patients and patients, patients and medical personnel. Sheets and napkins are used as non-sterile protective coatings for various surfaces (patient beds, couches, treatment tables etc.).

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".

The medical device complies with the applicable clauses of the following 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 16.07.2021.

Krasnogorsk, December 8th, 2021

Bunin A.F.
General Director
LLC Gexa – nonwoven materials