

Kadrovik d.o.o.

Cankarjev drevored 46

6310 Izola, Slovenia

# General Product Safety Directive (GPSD) Declaration

Product: NBR Teats for Droppers

Supplier: Kadrovik d.o.o.

Address: Cankarjev drevored 46, Izola, Slovenia

Contact Information: +38640194124

- 1. Product Identification:** The NBR Teats for droppers supplied by Kadrovik d.o.o. are intended for use with droppers to facilitate accurate liquid dispensing in pharmaceutical and liquid applications.
- 2. Compliance with General Product Safety Directive (GPSD):** We hereby declare that the NBR Teats for droppers supplied by Kadrovik d.o.o. comply with the requirements of the General Product Safety Directive (GPSD) (Directive 2001/95/EC). The NBR Teats meet the essential safety requirements, including but not limited to:
  - **Safety and Health:** The NBR Teats are made from high-quality Nitrile Butadiene Rubber (NBR), ensuring safe and reliable use in pharmaceutical and liquid dispensing applications.
  - **Risks Assessment:** The NBR Teats have undergone a comprehensive risk assessment to identify potential hazards and ensure safe and effective liquid dispensing.
  - **Instructions for Use:** Clear instructions for the proper application and usage of the NBR Teats are provided to users.
  - **Traceability:** We maintain appropriate documentation and traceability of the NBR Teats to ensure accountability and quick identification in case of safety concerns.
- 3. Compliance with Relevant Standards:** The NBR Teats supplied by Kadrovik d.o.o. are manufactured by reputable suppliers who ensure that the teats meet the relevant industry standards and guidelines, ensuring quality, safety, and performance. Some of the relevant standards that apply to the NBR Teats include:

- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
  - ISO 7886-3:2018 - Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization
  - ISO 11607-1:2019 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems
  - ISO 11607-2:2019 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes
4. Quality Assurance: We cooperate only with suppliers who maintain stringent quality control measures throughout the manufacturing process to ensure that each NBR Teat meets the required specifications and standards.
5. Continuous Safety Monitoring: We are committed to continuously monitoring the safety of the NBR Teats and promptly responding to any safety concerns that may arise. Customers are encouraged to report any issues related to the safety or performance of the supplied products to [info@packaging.si](mailto:info@packaging.si).

This General Product Safety Directive (GPSD) Declaration is issued by Kadrovik d.o.o. as a supplier to demonstrate our dedication to supplying safe and compliant NBR Teats for droppers used in pharmaceutical and liquid applications.

Andrej Koprivec, M.sc

CEO

Kadrovik d.o.o.

Izola, 10.6.2022