SAFETY AND OPERATING INSTRUCTIONS FOR POLYETHYLENE (PE) PRODUCTS

In accordance with Regulation (EU) 2023/988 of the European Parliament and of the Council (GPSR)

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1. GENERAL INFORMATION AND LEGAL BASIS

- **Purpose and Scope:** This manual has been developed to meet the requirements of the **General Product Safety Regulation (GPSR – EU 2023/988)**. It provides essential information regarding the safe use, storage, maintenance, and disposal of polyethylene (PE) products. It aims to minimize risks associated with product operation and ensure a high level of consumer health protection.
- **Responsible Entity (Importer):** These guidelines apply to the full range of polyethylene products offered by **Protectmedical Sp. z o.o.** Protectmedical ensures full product traceability in accordance with EU safety standards.
- **Material Characteristics:** Products made of polyethylene (LDPE/HDPE) are materials characterized by high chemical resistance, low specific mass, and high mechanical strength. Despite these advantages, as a polymer, polyethylene requires adherence to specific thermal and storage rigors to maintain its protective and functional parameters.
- **Safety and Responsibility:** Compliance with this manual is a mandatory condition for maintaining operational safety and the full durability of the products. Use contrary to the intended purpose or neglecting the indicated precautions may lead to the loss of the product's barrier properties and pose a threat to the user or the environment.

2. USAGE GUIDELINES

- **Intended Use:** Products must be used strictly according to their specific purpose (e.g., packaging, protection). Improper use may result in the voiding of the warranty and violation of general product safety requirements according to **Directive 2001/95/EC**.
- **Technical Condition Verification:** It is forbidden to use damaged products, including those that are cracked, deformed, or torn. Violation of the polymer structure disqualifies the product from further use, consistent with **ISO 9001** quality control procedures.
- **Thermal Safety:** Do not allow direct contact with open flames or high-temperature sources. Due to the physicochemical properties of polyethylene, products should not be used in temperatures exceeding **70°C (for LDPE)** or **90°C (for HDPE)** for extended periods, unless the technical specification of a specific model states otherwise.

- **Chemical Resistance:** Avoid contact with strong oxidants, concentrated acids, and aggressive organic solvents. Contact with such substances may lead to swelling, brittleness, or dissolution of the material, in accordance with **REACH** chemical safety guidelines.
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3. CLEANING AND MAINTENANCE

- **Cleaning Method:** Reusable products (if applicable) should be hand-washed in lukewarm water using mild detergents neutral to polymers.
- **Permissible Agents:** The use of strong corrosive agents, chlorine-based bleaches, and solvents is prohibited, as they can permanently damage the molecular bonds of the polyethylene and weaken its mechanical structure.
- **Drying Process:** After cleaning, products should be dried at room temperature in a well-ventilated area. Do not dry products on radiators or using hot air streams, as this could lead to thermal deformation.
- **Long-term Protection:** It is mandatory to protect products from prolonged UV radiation during the drying and storage process. According to the **EN ISO 4892** standard, exposure to sunlight accelerates the aging (photodegradation) of polyethylene
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4. STORAGE AND WAREHOUSING CONDITIONS

- **Storage Environment:** Products should be stored in a cool, dry place away from moisture sources to prevent material degradation and the weakening of bulk packaging seals.
- **UV Protection:** Protect the product from direct sunlight; according to **EN ISO 4892**, long-term UV exposure causes photodegradation of polyethylene, leading to brittleness and loss of barrier properties.
- **Mechanical Stability:** Do not store under excessive loads; stacking pallets or boxes too high may lead to permanent deformation, film cracking, and damage to the zip-lock mechanism in bags.
- **Thermal Control:** Avoid exposure to high temperatures that may lead to thermal deformation of packaging (T_{vicat} for LDPE is relatively low); optimal storage conditions should comply with the **General Product Safety Guidelines (Directive 2001/95/EC)**.
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5. PRECAUTIONS

- **Fire Safety:** Polyethylene is a flammable material. Avoid all contact with open flames and high heat sources. The combustion process may emit toxic gases. According to **EN ISO 11925-2** (reaction to fire), these materials require storage in dry and cool fire-protected conditions.

- **Chemical Resistance:** In the event of chemical spills, ensure the product does not come into contact with strong acids or organic solvents that could degrade the polymer structure. These guidelines align with the **REACH Regulation (EC No. 1907/2006)** regarding the safe use of chemicals.
- **Thermal Limitations:** Due to the low melting point of polyethylene (105–130°C), use in high temperatures, baking, or contact with hot surfaces is prohibited. Exceeding these thresholds violates safety standards for plastic products.
- **Packaging Integrity:** Do not use products with visible cracks, holes, or structural changes. Mechanical damage leads to loss of barrier properties and exposes the contents to contamination, which is critical in **ISO 9001** quality management systems.
- **Protection Against Mechanical Damage:** Avoid contact with sharp tools and excessive mechanical loads (especially with thin films), which can cause tears and loss of packaging functionality.
- **Food Contact Certification:** Products intended for food must bear clear marking (glass and fork pictogram) and a declaration of conformity with **Regulation EC 1935/2004** and **EU 10/2011**. The use of non-certified packaging for food storage is prohibited.
- **Child Safety (Suffocation Risk):** Due to the risk of asphyxiation, plastic bags and packaging must be kept out of reach of children. This complies with the requirements of **Directive 2001/95/EC** on general product safety.
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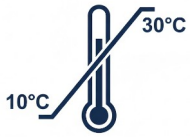
6. DISPOSAL AND RECYCLING

- **General Rules:** Polyethylene (LDPE/HDPE) is a fully mechanically recyclable material. According to **Directive 94/62/EC** on packaging and packaging waste, used products should be taken to a plastic waste collection point (yellow bin) to enable reprocessing.
- **Material Identification:** Before disposal, verify the recycling symbol on the packaging (e.g., **04 LDPE** for zip-lock bags or **02 HDPE** for aprons). Correct raw material identification according to Commission Decision **97/129/EC** facilitates the sorting and recovery process.
- **Waste Handling:** Used products, free from hazardous substances, should be handed over to municipal or industrial waste collection points. In case of contact with infectious material (e.g., in medical facilities), disposal must follow medical waste procedures.
- **Prohibition of Thermal Transformation:** It is strictly forbidden to burn products in domestic conditions or in facilities not designed for this purpose. Self-combustion of polyethylene leads to the emission of toxic substances and is contrary to environmental protection regulations.

7.PICTOGRAMS AND THEIR MEANINGS

	**Manufacturer Identification:** ProtectMedical Sp. z o.o., ul. Bukowa 49, 97-400 Bełchatów, Poland. www.protectmedical.eu
	**Instructions / Product Information:** The full manual is available on the manufacturer's website: www.protectmedical.eu
	**04 (LDPE) Symbol:** Indicates Low-Density Polyethylene, the material used for zip-lock bags. It complies with EU Directive 94/62/EC and EN 13430, confirming the material's suitability for multiple recycling and safe processing.
	**02 (PE-HD) Symbol:** Indicates High-Density Polyethylene, one of the safest plastics. It complies with REACH chemical safety standards and Directive 94/62/EC, guaranteeing full mechanical recyclability and usage safety.
	**PAP 21 Recycling (Non-corrugated cardboard):** Marking for high-grammage paper used for inserts or boxes. Indicates that the packaging is recyclable and should be disposed of in the blue paper waste bin.

	**Food Contact Symbol (Glass & Fork):** Confirms material safety and the absence of harmful substance migration into food. Guarantees neutral taste and odor, in compliance with EU Regulation 1935/2004.
	**CE Symbol (Conformité Européenne):** Official declaration that the product meets safety, health, and environmental requirements defined in EU directives. Allows for legal trade within the EEA.
	**EAC Symbol (EurAsian Conformity):** Confirms that the product has passed all assessment procedures and complies with the technical requirements of the Eurasian Customs Union (EAEU).
	**Protect from Sunlight / UV:** Indicates that the product must be stored in a place not exposed to direct sunlight to prevent material degradation.

	**Sposób przechowywania (temperatura)** – symbol określa bezpieczny zakres termiczny magazynowania (od -10°C do 30°C). Chroni to folię przed utratą elastyczności, osłabieniem zgrzewów-i-degradacją materiału.
	**Batch Number (LOT):** Unique alphanumeric code assigned to a specific production series. Essential for traceability, quality control, and the complaint process.
	**Packed by Weight (100 pcs):** Indicates that the quantity is determined by weight. Due to slight variations in individual item mass (bags, gloves, or aprons), the actual count may slightly deviate from the declared 100 units.
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	**Single Use Only (Crossed-out 2):** Indicates that the product (e.g., apron or glove) is intended for one-time use only. Reuse poses a risk of cross-contamination and loss of barrier properties.
	**Do Not Use if Packaging is Damaged:** Warning that compromised packaging (e.g., cuts in film) does not guarantee the product's original quality, cleanliness, or sterility.

9. PROTECTMEDICAL PRODUCT RANGE

Zip-lock bags (largest selection on the market), **Bags and carrier bags (T-shirt) on a roll**, **Stretch / Pallet films**, **Disposable PE gloves** (on header/tear-off), **PE protective aprons**, **Courier mailing bags** (Poly mailers), ...and more.

9. MANUFACTURER DATA

ProtectMedical Sp. z o.o. ul. Bukowa 49, 97-400 Bełchatów, Poland

E-mail / Web: www.protectmedical.eu