# GPSR Service Intro.


MEDTEX MEDSOLUTION LTD.

# GPSR (General Product Safety Regulation)

- GPSR provides a high level of consumer protection and a level playing field for businesses, thus improving the way the European Union’s (EU) internal market works.
- It replaces the current general product safety directive and food imitating product directive, which guarantee the safety of consumer goods sold both offline and online.
- Unlike the Directive it repeals, GPSR is directly applicable in the Member States.
- Applies from 13 December 2024.

# GPSR coverage

Includes

Excludes

- ✓ applies to new, used, repaired or reconditioned products:
  - available for distribution, consumption or use in the EU (‘placed or made available on the market’), whether for free or against payment, which are not covered by other specific EU product safety legislation,
  - subject to existing specific EU safety requirements regarding the risks and aspects that are not already covered therein;
- ✓ applies to products offered to consumers in the EU via all sales channels;
- ✗ does not apply to the following:
  - medicinal products for human or veterinary use,
  - food and feed,
  - living plants and animals, genetically modified organisms and microorganisms in contained use,
  - animal-derived and by-products,
  - plant protection products,
  - transport equipment operated by a service provider,
  - aircraft whose design, production, maintenance and operation pose a low safety risk,
  - antiques,
  - products clearly marked to be repaired or reconditioned prior to use.

GPSR applies to all e-commerce platforms!

# Safety requirements


Economic operators will place or make available on the market only safe products (general safety requirement).
The safety of products must be assessed, taking into account, in particular, the following criteria:

- the characteristics of the product, such as design, technical features, composition, packaging and instructions;
- the effect on other products;
- the presentation of the product, the labelling, any warnings and safety instructions and information;
- the categories of consumers using the product;
- the appearance of the product, in particular food-imitating or child-appealing aspects;
- the cybersecurity features and any evolving, learning and predictive functionalities of the product.

This regulation also provides for cases where a product is presumed to be safe. Such cases include products in conformity with relevant European standards referenced in the *Official Journal of the European Union*.

Other elements that can be taken into account for assessing the safety of a product are national and international standards, voluntary certification schemes, good-practice codes and reasonable consumer expectations.

# Key Responsibilities of Authorised Representative

**1. Product Compliance Verification**
- Ensure that a **Declaration of Conformity** (or equivalent) and **Technical Documentation** are available and kept up-to-date.
- Confirm that the product meets the **General Safety Requirements** under the GPSR.

**2. Documentation Management**
- Keep a copy of the **Declaration of Conformity** and **Technical Documentation** for at least **10 years** after the product is placed on the market.
- Provide these documents to national authorities upon request.

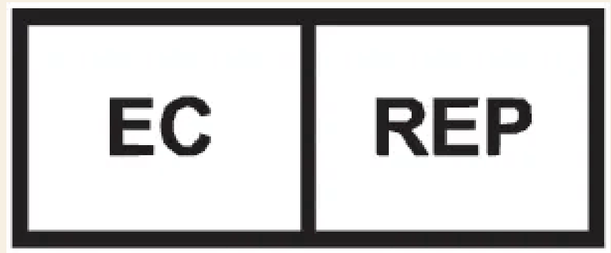
**3. Market Surveillance Support**
- Collaborate with **market surveillance authorities** and provide any information necessary to demonstrate product compliance.
- Inform the manufacturer of any non-compliance concerns or consumer safety risks.

**4. Incident Reporting**
- If the AR becomes aware of a product presenting **risks** to health and safety, they must notify the manufacturer and relevant **market surveillance authorities**.
- Assist in product recalls or corrective actions when necessary.

**5. Consumer Communication**
- Ensure that the manufacturer provides clear instructions and safety information for consumers in the appropriate **EU language(s)**.
- Facilitate responses to consumer complaints and regulatory inquiries.

**6. Identification and Contact**
- Ensure their **name, address, and contact details** are included on the product, packaging, or accompanying documentation.

# Other services provided by Medtex




Authorised representative
service for MDR/IVDR & MSR

Legal importer
service for MDR/IVDR

Cosmetics product
registration in EU & UK

# Contact us for more information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