

The European Union's <u>General Product Safety Regulation</u> (Regulation (EU) 2023/988, or GPSR) fully replaced the General Product Safety Directive (GPSD) on **December 13, 2024**. It applies to **all consumer products placed on the EU market**, whether sold in physical retail or via digital platforms.

This regulation applies not only to EU-based companies but also to **non-EU manufacturers**, **brand owners**, **and importers**, including those based in the United States, Canada, UK, Switzerland, and Australia, if they sell directly to EU consumers or through marketplaces.

# **Key Changes Introduced Under the GPSR**

### 1. Expanded Scope and Definitions

The **GPSR** introduces clarified definitions and expands legal obligations:

- **Manufacturer**: A company that produces a product or has one produced and markets it under its name or trademark.
- Importer: An EU-based business that places a product from a third country onto the EU market.
- **Distributor and Fulfilment Service Provider**: These parties now carry responsibility depending on how products move through the supply chain.
- A product is only "safe" if it poses no risk under normal or foreseeable conditions, taking into account:
  - Misuse scenarios
  - Digital components and updates
  - Vulnerable user groups (e.g., children, elderly)

#### 2. Risk Assessment and Technical Documentation

All manufacturers must perform a **GPSR-compliant risk assessment** and compile supporting documentation in a **Technical File**, which must be retained for **10 years**. As outlined in **EaseCert's Technical Documentation Guide**, this file must include:

- Product details, specifications, and descriptions
- Risk analysis and mitigation measures
- Conformity declarations and testing reports
- Labeling proofs, manuals, and safety instructions
- Traceability data and surveillance processes
- Contact details for the manufacturer, importer, and EU Responsible Person

This documentation must be provided to EU authorities on request, without delay.



### 3. Mandatory EU-Based Responsible Person

Non-EU manufacturers must appoint a Responsible Person (RP) within the EU.

As explained in **EaseCert's RP Guide**:

- The RP is legally responsible for storing compliance documentation, communicating with EU regulators, and coordinating any required corrective action.
- Acceptable roles include:
  - Authorised Representative
  - o Importer
  - o Fulfilment Service Provider
  - o Distributor (if formally designated)
- The RP's full name, postal address, and email **must be printed** on the product, its packaging, or the enclosed documentation.
- An anonymous or non-EU RP is not permitted.

This is a **non-negotiable requirement** for listing products on EU marketplaces or placing goods in the EU market.

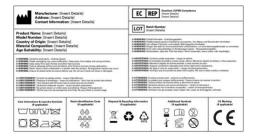
## 4. Stronger Traceability and Labelling Requirements

Labeling now falls under stricter rules. According to **EaseCert's Labelling Guide**, the following must be included:

- Product identifier (type, model, serial/batch number)
- Name and contact information of the manufacturer or importer
- Responsible Person's name and address
- · Required warning messages and safety instructions
- Translations for each language where the product is sold
- Durable, physical labels (QR codes alone are not accepted)

Missing or incorrect labels are among the top causes of enforcement action under GPSR.

For reference, download our **EaseCert Product Label Template**.





### 5. GPSR Risk Analysis Process

Following **EaseCert's Risk Assessment Framework**, each product must undergo a structured review for:

- Physical and Mechanical Hazards
- Flammability / Thermal Hazards
- Chemical Hazards
- Electrical Hazards
- Hygiene Hazards
- Radiation Hazards

All risks must be rated (Critical, Major, Minor) and documented in the technical file, along with preventive design measures and warnings.

Download our **GPSR Risk Analysis Template** for a structured approach to evaluating product safety risks.





#### 6. EU Safety Gate Registration Requirements

Under GPSR Article 25, online marketplace operators and sellers must register via the **EU Safety Gate – Online Marketplace Module**. This ensures streamlined communication between sellers and EU authorities for incident tracking, enforcement, and recall coordination.

#### According to **EaseCert's EU Safety Gate Registration Guide**:

- Registration is mandatory for sellers offering products via their own online stores (e.g., Shopify)
- The portal requires:
  - Business identification
  - Responsible Person details (if applicable)
  - Declaration that products comply with GPSR requirements
- Once registered, sellers must respond promptly to requests from market surveillance authorities

Failure to register may result in deactivation of listings, product bans, or marketplace restrictions.

### 7. Compliance Checklist for Importers and Manufacturers

To comply with GPSR, businesses must:

- 1. Appoint an EU-Based Responsible Person
- 2. Perform and Document a Risk Assessment
- 3. Compile a Complete Technical File
- 4. Ensure Proper and Multilingual Labelling
- 5. Register with the EU Safety Gate (Online Sellers)
- 6. Update Online Listings to Include RP Details
- 7. Maintain Records for at Least 10 Years
- 8. Stay Current with EU Regulatory Guidance

### 8. Penalties for Non-Compliance

GPSR enforcement includes:

- Product bans or market recalls, fines and legal sanctions
- Delisting from e-commerce platforms
- Public safety alerts (via RAPEX/Safety Gate)
- Reputational harm and blocked market access

EU authorities are now equipped for faster enforcement, including digital inspection and monitoring of online stores.



#### 9. Final Thoughts

The GPSR is a sweeping regulatory shift. It places new burdens, but also clearer rules, on how companies can legally place products in the EU market. Non-EU businesses must now plan for:

- Documentation
- Risk transparency
- Accountability via a named Responsible Person
- Registration with digital safety platforms like the EU Safety Gate

<u>EaseCert</u> offers tailored, fixed-fee GPSR compliance services (EU Responsible Person representation, risk assessments, technical file documentation, labeling review, and Safety Gate support), ideal for importers, brands, and SMEs selling to the EU.

#### 10. Learn More

- EaseCert: EU Safety Gate Registration Guide
- EaseCert: GPSR Responsible Person What EU Importers Must Know
- EaseCert: GPSR Labelling Requirements
- EaseCert: GPSR Technical File Documentation Guide
- EaseCert: The GPSR Risk Analysis Process
- EU Safety Gate RAPEX Alerts
- Regulation (EU) 2023/988 Official Journal