

# GENERAL PRODUCT SAFETY - CHECKLIST OF REQUIREMENTS MAKING PRODUCTS AVAILABLE ON THE MARKET

This supporting document is here to help you retrieve the set of requirements which apply to you depending on your situation regarding Regulation 2023/988 of 10 May 2023 on general product safety (GPSR).

This supporting document represent EDANA's interpretation of legal requirements and it is designed to assist in achieving compliance but may not cover every aspect of legal obligations. By using it, you recognize that it does not absolve your Company from its responsibility to comply with all relevant legal obligations.

This supporting document focuses on the list of post-market requirements, and requirements to comply with in case of an exceptional event, i.e. when a product is, or suspected to be dangerous. It does not provide the list of requirements to comply with on a regular basis, when making a product available on the EU market. In this last scenario, please refer to the annex of the guidelines on the requirements related to making a product available on the market.

When using this supporting document, the first step is to assess my nature as an economic operator under the GPSR.

The second step is to check whether I complied with all the requirements listed in the worksheet which is relevant for me.

In the worksheets, the provisions of the GPSR which are also relevant for products falling within the scope of the Cosmetic Products Regulation and the Medical Devices Regulation are marked by a red circle.



## STEP 1 - WHAT ECONOMIC OPERATOR AM I UNDER THE GPSR?

Under the GPSR, an economic operator is either the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with the GPSR.

Which situation described below suits me the best?

### I AM ESTABLISHED IN THE EU, AND:

I am a natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under my name or trademark.	<p><b>I am a MANUFACTURER</b></p> <p>→ Refer to the <b>EU MANUFACTURER</b> worksheet</p>
I am a natural or legal person who places a product on the market under my natural or legal person's name or trademark.	<p><b>I am a MANUFACTURER</b></p> <p>→ Refer to the <b>EU MANUFACTURER</b> worksheet</p>
I am a natural or legal person, other than the manufacturer, that substantially modifies the product*.	<p><b>I am a MANUFACTURER for the part of the product affected by the modification or for the entire product if the substantial modification has an impact on its safety.</b></p> <p>→ Refer to the <b>EU MANUFACTURER</b> worksheet</p>
I am a natural or legal person established within the Union who has received a written mandate from a manufacturer to act on that manufacturer's behalf in relation to specified tasks with regard to the manufacturer's obligations under the GPSR.	<p><b>I am an AUTHORISED REPRESENTATIVE who is responsible for the whole or only for part of the application of the GPSR, depending on the mandate delivered by the MANUFACTURER.</b></p> <p>→ Refer to the <b>EU MANUFACTURER</b> worksheet</p>
I am a natural or legal person established within the Union who places a product from a third country on the Union market.	<p><b>I am an IMPORTER</b></p> <p>→ Refer to the <b>IMPORTER</b> worksheet</p>
<p>I am a natural or legal person in the supply chain who makes a product available on the market. I do not manufacture the product or have the product designed or manufactured, and I do not market that product under my name or trademark.</p> <p>I do not place the product from a third country on the Union market.</p>	<p><b>I am a DISTRIBUTOR</b></p> <p>→ Refer to the <b>DISTRIBUTOR</b> worksheet</p>
I am a natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in Article 2, point (1) of Directive 97/67/EC of the European Parliament and of the Council (27), parcel delivery services as defined in Article 2, point (2) of Regulation (EU) 2018/644 of the European Parliament and of the Council (28), and any other postal services or freight transport services.	<p><b>I am a FULFILMENT SERVICE PROVIDER</b></p>

## STEP 1 - WHAT ECONOMIC OPERATOR AM I UNDER THE GPSR?

IF I AM NOT ESTABLISHED IN THE EU, AND I WANT TO PLACE A PRODUCT ON THE EU MARKET, I SHALL APPOINT AN AUTHORISED REPRESENTATIVE:

→ Refer to the **AUTHORISED REPRESENTATIVE** and **NON-EU MANUFACTURER** worksheet

\* A modification of a product, by physical or digital means, shall be deemed to be substantial where it has an impact on the safety of the product and the following criteria are met:

- (a) the modification changes the product in a manner which was not foreseen in the initial risk assessment of the product;
- (b) the nature of the hazard has changed, a new hazard has been created or the level of risk has increased because of the modification; and

## STEP 2 - EU MANUFACTURER

**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

Authorised representatives should identify which of the requirements below are included in their mandate.

### Requirement

### GPSR (Art. ...)

#### 1. General safety requirement

5.

1.1. When assessing whether the product is a safe product, I took into account at least the following aspects:

6.1.

the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation, use and maintenance		6.1.(a)
the effect on other products, where it is reasonably foreseeable that the product will be used with other products, including the interconnection of those products		6.1.(b)
the effect that other products might have on the product to be assessed, where it is reasonably foreseeable that other products will be used with that product, including the effect of non-embedded items that are meant to determine, change or complete the way the product to be assessed works, which has to be taken into consideration when assessing the safety of the product to be assessed		6.1.(c)
the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product		6.1.(d)
the categories of consumers using the product, in particular by assessing the risk for vulnerable consumers such as children, older people and persons with disabilities, as well as the impact of gender differences on health and safety		6.1.(e)
the appearance of the product where it is likely to lead consumers to use the product in a way different to what it was designed for, and in particular: (i) where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics and might therefore be placed in the mouth, sucked or ingested by consumers, especially by children; (ii) where a product, although neither designed nor intended for use by children, is likely to be used by children or resembles an object commonly recognised as <u>appealing to or intended for use by children because of its design, packaging or characteristics</u>		6.1.(f)
when required by the nature of the product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, where such an influence might have an impact on the safety of the product, including the possible loss of interconnection		6.1.(g)
when required by the nature of the product, the evolving, learning and predictive functionalities of the product.		6.1.(h)

**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

Authorised representatives should identify which of the requirements below are included in their mandate.

### 1.2. Presumption of conformity with the general safety requirement

7.

The product:

conforms to relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		7.1.(a)
conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law		7.1.(b)

If one of the upper boxes is checked, the product is presumed safe.

If none of the upper boxes is checked, when assessing whether the product is a safe product, I took into account the following elements in particular, when available:

8.

European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		8.1.(a)
international standards		8.1.(b)
international agreements		8.1.(c)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law		8.1.(d)
Commission recommendations or guidelines on product safety assessment		8.1.(e)
national standards drawn up in the Member State in which the product is made available		8.1.(f)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees		8.1.(g)
product safety codes of good practice in force in the sector concerned		8.1.(h)
reasonable consumer expectations concerning safety		8.1.(i)
safety requirements adopted by the European Commission		8.1.(j)

When placing the product on the market, I ensured that my product has been designed and manufactured in accordance with the general safety requirement.

9.1.

**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

Authorised representatives should identify which of the requirements below are included in their mandate.

### 2. Obligations of manufacturers

9

#### 2.1. Before placing the product on the market, I:

carried out an internal risk analysis		9.2.
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drawn up technical documentation containing at least:

a general description of the product		9.2.
its essential characteristics relevant for assessing its safety		9.2.

Where appropriate with regard to possible risks related to the product, the technical documentation shall also contain, as applicable:

an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf (where appropriate with regard to possible risks related to the product)		9.2.(a)
the list of any relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
international standards (where appropriate with regard to possible risks related to the product)		9.2.(b)
international agreements (where appropriate with regard to possible risks related to the product)		9.2.(b)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
Commission recommendations or guidelines on product safety assessment (where appropriate with regard to possible risks related to the product)		9.2.(b)
national standards drawn up in the Member State in which the product is made available (where appropriate with regard to possible risks related to the product)		9.2.(b)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees (where appropriate with regard to possible risks related to the product)		9.2.(b)

## STEP 2 - EU MANUFACTURER

**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

*Authorised representatives should identify which of the requirements below are included in their mandate.*

product safety codes of good practice in force in the sector concerned (where appropriate with regard to possible risks related to the product)		9.2.(b)
reasonable consumer expectations concerning safety (where appropriate with regard to possible risks related to the product)		9.2.(b)
safety requirements adopted by the European Commission (where appropriate with regard to possible risks related to the product)		9.2.(b)
Where any of the European standards, health and safety requirements or aforementioned elements have been only partly applied, I identified the parts which have been applied.		9.2.

I ensured that the technical documentation is up to date.		9.3.
I will keep the technical documentation at the disposal of the market surveillance authorities for a period of 10 years after the product has been placed on the market and make that documentation available to those authorities upon request		9.3.

If my product is produced in series, I ensured that procedures are in place for them to remain in conformity with the general safety requirement		9.4.
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I ensured that my product bears a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.		9.5.
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I indicated on the product or, where that is not possible, on its packaging or in a document accompanying the product my name, my registered trade name or registered trade mark, my postal and electronic address and, where different, the postal or electronic address of the single contact point at which I can be contacted.		9.6.
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If my product cannot be used safely and as intended by me without instructions and safety information, I ensured that my product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		9.7.
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I made publicly available communication channels such as a telephone number, electronic address or dedicated section of my website, taking into account accessibility needs for persons with disabilities, enabling consumers to submit complaints and to inform me of any accident or safety issue they have experienced with my product.		9.11.
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**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

Authorised representatives should identify which of the requirements below are included in their mandate.

### 2.2. In the case of distance sales

19.

If I make the product available on the market online or through other means of distance sales, the offer of this product clearly and visibly indicates at least the following information:

my name, registered trade name or registered trade mark, as well as the postal and electronic address at which I can be contacted		19.(a)
if I am not established in the Union, the name, postal and electronic address of the responsible person		19.(b)
information allowing the identification of the product, including a picture of it, its type and any other product identifier		19.(c)
any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		19.(d)

### 3. Duties as the responsible person for the product placed on the Union market

16.

I regularly checked:

that the product complies with the technical documentation		16.2
that the product bear the label to identify the product, the label to identify the manufacturer, and the instructions and safety information.		16.2
that I can provide documented evidence of the aforementioned checks performed upon request by the market surveillance authorities.		16.2

When placing the product on the EU market, I ensured that:

I am established in the Union.		16.1
the technical documentation has been drawn up and can be made available to market surveillance authorities upon request.		16.1
my name, registered trade name or registered trade mark, and contact details, including the postal and electronic address, are indicated on the product or on its packaging, the parcel or an accompanying document.		16.3



**EU MANUFACTURERS** (or **AUTHORISED REPRESENTATIVES** appointed by EU manufacturers) should assess whether the product checks the boxes below before placing it on the market.

Authorised representatives should identify which of the requirements below are included in their mandate.

**Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.**

**AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.

## Requirement

## GPSR (Art. ...)

### 1. General safety requirement

5.

#### 1.1. When assessing whether the product is a safe product, the manufacturer took into account at least the following aspects:

6.1.

the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation, use and maintenance		6.1.(a)
the effect on other products, where it is reasonably foreseeable that the product will be used with other products, including the interconnection of those products		6.1.(b)
the effect that other products might have on the product to be assessed, where it is reasonably foreseeable that other products will be used with that product, including the effect of non-embedded items that are meant to determine, change or complete the way the product to be assessed works, which has to be taken into consideration when assessing the safety of the product to be assessed		6.1.(c)
the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product		6.1.(d)
the categories of consumers using the product, in particular by assessing the risk for vulnerable consumers such as children, older people and persons with disabilities, as well as the impact of gender differences on health and safety		6.1.(e)
the appearance of the product where it is likely to lead consumers to use the product in a way different to what it was designed for, and in particular: (i) where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics and might therefore be placed in the mouth, sucked or ingested by consumers, especially by children; (ii) where a product, although neither designed nor intended for use by children, is likely to be used by children or resembles an object commonly recognised as <u>appealing to or intended for use by children because of its design, packaging or characteristics</u>		6.1.(f)
when required by the nature of the product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, where such an influence might have an impact on the safety of the product, including the possible loss of interconnection		6.1.(g)
when required by the nature of the product, the evolving, learning and predictive functionalities of the product.		6.1.(h)

## STEP 2 - AUTHORISED REPRESENTATIVE and NON-EU MANUFACTURER

**Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.**

**AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.

### Requirement

### GPSR (Art. ...)

#### 1.2. Presumption of conformity with the general safety requirement

7.

The product:

conforms to relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		7.1.(a)
conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law		7.1.(b)

If one of the upper boxes is checked, the product is presumed safe.

If none of the upper boxes is checked, when assessing whether the product is a safe product, the manufacturer took into account the following elements in particular, when available:

8.

European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		8.1.(a)
international standards		8.1.(b)
international agreements		8.1.(c)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law		8.1.(d)
Commission recommendations or guidelines on product safety assessment		8.1.(e)
national standards drawn up in the Member State in which the product is made available		8.1.(f)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees		8.1.(g)
product safety codes of good practice in force in the sector concerned		8.1.(h)
reasonable consumer expectations concerning safety		8.1.(i)
safety requirements adopted by the European Commission		8.1.(j)

When placing the product on the market, the manufacturer ensured that the product has been designed and manufactured in accordance with the general safety requirement.

9.1.

**Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.**

**AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.

## Requirement

## GPSR (Art. ...)

### 2. Obligations of non-EU manufacturers to be checked by the authorised representatives

9

#### 2.1. Before placing the product on the market, the manufacturer:

carried out an internal risk analysis		9.2.
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drawn up technical documentation containing at least:

a general description of the product		9.2.
its essential characteristics relevant for assessing its safety		9.2.

Where appropriate with regard to possible risks related to the product, the technical documentation shall also contain, as applicable:

an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf (where appropriate with regard to possible risks related to the product)		9.2.(a)
the list of any relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
international standards (where appropriate with regard to possible risks related to the product)		9.2.(b)
international agreements (where appropriate with regard to possible risks related to the product)		9.2.(b)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
Commission recommendations or guidelines on product safety assessment (where appropriate with regard to possible risks related to the product)		9.2.(b)

## STEP 2 - AUTHORISED REPRESENTATIVE and NON-EU MANUFACTURER

**Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.**

**AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.

Requirement	GPSR (Art. ...)	
national standards drawn up in the Member State in which the product is made available (where appropriate with regard to possible risks related to the product)		9.2.(b)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees (where appropriate with regard to possible risks related to the product)		9.2.(b)
product safety codes of good practice in force in the sector concerned (where appropriate with regard to possible risks related to the product)		9.2.(b)
reasonable consumer expectations concerning safety (where appropriate with regard to possible risks related to the product)		9.2.(b)
safety requirements adopted by the European Commission (where appropriate with regard to possible risks related to the product)		9.2.(b)
Where any of the European standards, health and safety requirements or aforementioned elements have been only partly applied, the manufacturer identified the parts which have been applied.		9.2.
The manufacturer ensured that the technical documentation is up to date.		9.3.
The manufacturer will keep the technical documentation at the disposal of the market surveillance authorities for a period of 10 years after the product has been placed on the market and make that documentation available to those authorities upon request		9.3.
If the product is produced in series, the manufacturer ensured that procedures are in place for them to remain in conformity with the general safety requirement		9.4.
The manufacturer ensured that the product bears a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.		9.5.
The manufacturer indicated on the product or, where that is not possible, on its packaging or in a document accompanying the product the name, the registered trade name or registered trade mark, the postal and electronic address and, where different, the postal or electronic address of the single contact point at which the manufacturer can be contacted.		9.6.
If the product cannot be used safely and as intended by the manufacturer without instructions and safety information, the manufacturer ensured that the product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		9.7.

## STEP 2 - AUTHORISED REPRESENTATIVE and NON-EU MANUFACTURER

*Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.*

***AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.*

Requirement	GPSR (Art. ...)	
The manufacturer made publicly available communication channels such as a telephone number, electronic address or dedicated section of the website, taking into account accessibility needs for persons with disabilities, enabling consumers to submit complaints and to inform me of any accident or safety issue they have experienced with the product.		9.11.

### 2.2. In the case of distance sales

19.

If the manufacturer makes the product available on the market online or through other means of distance sales, the offer of this product clearly and visibly indicates at least the following

the name, registered trade name or registered trade mark, as well as the postal and electronic address at which the manufacturer can be contacted		19.(a)
the name, postal and electronic address of the responsible person		19.(b)
information allowing the identification of the product, including a picture of it, its type and any other product identifier		19.(c)
any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		19.(d)

*Non-EU Manufacturers shall appoint an Authorised representative in order to place their product on the EU market.*

***AUTHORISED REPRESENTATIVES** appointed by **NON-EU MANUFACTURERS** should at least control that the non-EU manufacturer complied with the relevant obligations (highlighted in yellow) and that they complied with their own obligations themselves (highlighted in blue). In this situation, the mandate of the authorised representatives could also include the rest of the requirements below.*

Requirement	GPSR (Art. ...)
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### 3. Duties as the responsible person for the product placed on the Union market

16.

The authorised representative regularly checked:

that the product complies with the technical documentation		16.2
that the product bear the label to identify the product, the label to identify the manufacturer, and the instructions and safety information.		16.2
that the authorised representative can provide documented evidence of the aforementioned checks performed upon request by the market surveillance		16.2

When placing the product on the EU market, the authorised representative ensured that:

the authorised representative is established in the Union.		16.1
the technical documentation has been drawn up and can be made available to market surveillance authorities upon request.		16.1
the name (the one of the authorised representative), registered trade name or registered trade mark, and contact details, including the postal and electronic address, are indicated on the product or on its packaging, the parcel or an accompanying document		16.3

### Requirement

GPSR (Art. ...)

#### 1. General safety requirement

5.

##### 1.1. When assessing whether the product is a safe product, I took into account at least the following aspects:

6.1.

the characteristics of the product, including its design, technical features, composition, packaging, instructions for assembly and, where applicable, for installation, use and maintenance		6.1.(a)
the effect on other products, where it is reasonably foreseeable that the product will be used with other products, including the interconnection of those products		6.1.(b)
the effect that other products might have on the product to be assessed, where it is reasonably foreseeable that other products will be used with that product, including the effect of non-embedded items that are meant to determine, change or complete the way the product to be assessed works, which has to be taken into consideration when assessing the safety of the product to be assessed		6.1.(c)
the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product		6.1.(d)
the categories of consumers using the product, in particular by assessing the risk for vulnerable consumers such as children, older people and persons with disabilities, as well as the impact of gender differences on health and safety		6.1.(e)
the appearance of the product where it is likely to lead consumers to use the product in a way different to what it was designed for, and in particular: (i) where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics and might therefore be placed in the mouth, sucked or ingested by consumers, especially by children; (ii) where a product, although neither designed nor intended for use by children, is likely to be used by children or resembles an object commonly recognised as <u>appealing to or intended for use by children because of its design, packaging or characteristics</u>		6.1.(f)
when required by the nature of the product, the appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, where such an influence might have an impact on the safety of the product, including the possible loss of interconnection		6.1.(g)
when required by the nature of the product, the evolving, learning and predictive functionalities of the product.		6.1.(h)



### Requirement

GPSR (Art. ...)

#### 1.2. Presumption of conformity with the general safety requirement

7.

The product:

conforms to relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		7.1.(a)
conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law		7.1.(b)

If one of the upper boxes is checked, the product is presumed safe.

If none of the upper boxes is checked, when assessing whether the product is a safe product, I took into account the following elements in particular, when available:

8.

European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012		8.1.(a)
international standards		8.1.(b)
international agreements		8.1.(c)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law		8.1.(d)
Commission recommendations or guidelines on product safety assessment		8.1.(e)
national standards drawn up in the Member State in which the product is made available		8.1.(f)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees		8.1.(g)
product safety codes of good practice in force in the sector concerned		8.1.(h)
reasonable consumer expectations concerning safety		8.1.(i)
safety requirements adopted by the European Commission		8.1.(j)

Before placing the product on the market, I ensured that the product complies with the general safety requirement.

11.1.

## Requirement

GPSR (Art. ...)

### 2. Obligations of importers

11.

#### 2.1. Before placing the product on the market, I ensured that the manufacturer:

carried out an internal risk analysis		9.2.
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drawn up technical documentation containing at least:

a general description of the product		9.2.
its essential characteristics relevant for assessing its safety		9.2.
an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any reports related to tests conducted by the manufacturer or by another party on their behalf (where appropriate with regard to possible risks related to the product)		9.2.(a)
the list of any relevant European standards or parts thereof as far as the risks and risk categories covered by those standards are concerned, the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012 (where appropriate with regard to possible risks related to the product)		9.2.(b)
international standards (where appropriate with regard to possible risks related to the product)		9.2.(b)
international agreements (where appropriate with regard to possible risks related to the product)		9.2.(b)
voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law (where appropriate with regard to possible risks related to the product)		9.2.(b)
Commission recommendations or guidelines on product safety assessment (where appropriate with regard to possible risks related to the product)		9.2.(b)
national standards drawn up in the Member State in which the product is made available (where appropriate with regard to possible risks related to the product)		9.2.(b)
the state of the art and technology, including the opinion of recognised scientific bodies and expert committees (where appropriate with regard to possible risks related to the product)		9.2.(b)
product safety codes of good practice in force in the sector concerned (where appropriate with regard to possible risks related to the product)		9.2.(b)
reasonable consumer expectations concerning safety (where appropriate with regard to possible risks related to the product)		9.2.(b)

### Requirement

### GPSR (Art. ...)

safety requirements adopted by the European Commission (where appropriate with regard to possible risks related to the product)		9.2.(b)
Where any of the European standards, health and safety requirements or aforementioned elements have been only partly applied, the manufacturer identified the parts which have been applied.		9.2.
I ensured that the product bears a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.		9.5.
I indicated on the product or, where that is not possible, on its packaging or in a document accompanying the product its name, its registered trade name or registered trade mark, its postal and electronic address and, where different, the postal or electronic address of the single contact point at which the manufacturer can be contacted.		9.6.

### 2.2. Before placing the product on the market, I ensured that:

I indicated my name, my registered trade name or registered trade mark, my postal and electronic address and, where different, the postal or electronic address of the single contact point at which I can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product.		11.3
any additional label does not obscure any information required by Union law on the label provided by the manufacturer.		11.3
the product I imported is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market, except where the product can be used safely and as intended by the manufacturer <del>without such instructions and safety information</del>		11.4
while the product was under my responsibility, storage or transport conditions did not jeopardise its conformity with the general safety requirement, nor the label to identify the product or the label to identify the manufacturer.		11.5
the communication channels of the manufacturer, such as a telephone number, electronic address or dedicated section of its website, are publicly available to consumers, thereby allowing them to present complaints and communicate any accident or safety issue they have experienced with the product. If such channels are not available, I provided for them, taking into account accessibility needs for persons with disabilities.		11.9

### 2.3. In the case of distance sales

19.

If I make the product available on the market online or through other means of distance sales, the offer of this product clearly and visibly indicates at least the following information:

name, registered trade name or registered trade mark of the manufacturer, as well as the postal and electronic address at which they can be contacted		19.(a)
where the manufacturer is not established in the Union, the name, postal and electronic address of the responsible person		19.(b)
information allowing the identification of the product, including a picture of it, its type and any other product identifier		19.(c)

### Requirement

### GPSR (Art. ...)

any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		19.(d)
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### 3. Duties as the responsible person for the product placed on the Union market

16.

I regularly checked:

that the product complies with the technical documentation		16.2
that the product bear the label to identify the product, the label to identify the manufacturer, and the instructions and safety information.		16.2
that I can provide documented evidence of the aforementioned checks performed upon request by the market surveillance authorities.		16.2

When placing the product on the EU market, I ensured that:

I am established in the Union.		16.1
the technical documentation has been drawn up and can be made available to market surveillance authorities upon request.		16.1
my name, registered trade name or registered trade mark, and contact details, including the postal and electronic address, are indicated on the product or on its packaging, the parcel or an accompanying document		16.3

### Requirement

GPSR (Art. ...)

#### 1. Obligations of distributors

12.

##### 1.1. Before making a product available on the market, I verified that the manufacturer:

12.1.

ensured that the product bears a type, batch or serial number or other element enabling the identification of the product and which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.		9.5
indicated on the product or, where that is not possible, on its packaging or in a document accompanying the product its name, its registered trade name or registered trade mark, its postal and electronic address and, where different, the postal or electronic address of the single contact point at which the manufacturer can be contacted.		9.6.
ensured that its product is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market, if its product cannot be used safely and as intended by me without instructions and safety information.		9.7.

##### 1.2. Before making a product available on the market, I verified that the importer:

12.1.

indicated its name, its registered trade name or registered trade mark, its postal and electronic address and, where different, the postal or electronic address of the single contact point at which the importer can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product.		11.3
did not obscure with an additional label any information required by Union law on the label provided by the manufacturer.		11.3
ensured that the product they imported is accompanied by clear instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information.		11.4

##### 1.3. Before making a product available on the market, I ensured that:

12.2.

while the product was under my responsibility, storage or transport conditions did not jeopardise its conformity with the general safety requirement, nor the label to identify the product, the label to identify the manufacturer or the importer, or the instructions and safety information.		12.2.
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##### 1.4. In the case of distance sales

19.

If I make the product available on the market online or through other means of distance sales, the offer of this product clearly and visibly indicates at least the following information:

name, registered trade name or registered trade mark of the manufacturer, as well as the postal and electronic address at which they can be contacted		19.(a)
where the manufacturer is not established in the Union, the name, postal and electronic address of the responsible person		19.(b)
information allowing the identification of the product, including a picture of it, its type and any other product identifier		19.(c)

### Requirement

### GPSR (Art. ...)

any warning or safety information to be affixed to the product or to the packaging or included in an accompanying document in accordance with the GPSR or the applicable Union harmonisation legislation in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available on the market.		19.(d)
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