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Placing products on the internal market of the European Economic Area

Procedures for economic operators and the services of testing, inspection and certification organisations in the Czech Republic as an EU Member State

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Introduction

This document builds on the publications issued by the Association of Accredited and Authorised Organisations (AAAO) between 2013 and 2024. It is primarily intended for economic operators placing products on the market within the European Economic Area, particularly those based in the Czech Republic. It may be useful for staff of authorised bodies, notified bodies, government authorities, professionals in the field and end-users of products.

It summarises the general principles governing the placing on the market of products that pose an increased risk to legitimate interests. This document cites both European and Czech legislation; the full texts of the cited legislation and other useful links can be accessed directly from the text of this handbook.

For further details on individual chapters, links are provided to the relevant sections of the ÚNMZ **'Placing Products on the Market'** portal**.** Overviews of harmonised and designated standards for individual sectors are linked to **the ÚNMZ Information Portal – Product Sectors**. Given that the construction products sector involves a great many differences, **a** dedicated **ÚNMZ Information Portal – Construction Products** has been developed for this purpose. Relevant information on construction products is therefore mostly linked directly to sections of this portal. All of the above-mentioned ÚNMZ portals are updated monthly.

For users of the printed version, the document on the front page features **a QR code** which, when scanned, directs the user to a web page containing the online text of this interactive guide.

This document is updated monthly with regard to the regulations cited; the updated version can be downloaded in Word format at **https://www.nlfnorm.cz/informacni-portal/1668/publikace-aaao-uvadeni-vyrobku-na-trh**. This web address also lists the changes made to this document during the month in question.

Other regulations relating to individual sectors are updated directly on the above-mentioned portals; they are not subject to updates in this handbook and are merely linked to here.

1. Terms and definitions

The following table provides direct links to the articles or sections of those horizontal EU and Czech Republic documents where the key terms and definitions relating to the placing of products on the market can be found. The individual terms and definitions overlap with one another:

EU/Czech Republic legislation	Link to definitions
Regulation **(EU) 2023/988** of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council (consolidated version including amendment **(EU) 2024/2748**)	**Article 3**
Regulation **(EU) 2019/515** of the European Parliament and of the Council on the mutual recognition of goods lawfully placed on the market in another Member State and repealing Regulation (EC) No 764/2008	**Article 3**

EU/Czech Republic legislation	Link to definitions
Regulation **(EU) 2019/1020** of the European Parliament and of the Council on market surveillance and compliance of products with regulations, and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (consolidated version of 12 August 2026, including Amendment **(EU) 2025/40,** which applies from 12 August 2026, excluding Amendment **(EU) 2025/14),** which applies from 29 January 2028)	**Article 3**
Regulation (EU) No **1025/2012** of the European Parliament and of the Council **on European standardisation**, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC, and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (consolidated version)	**Article 2**
Act No. **22/1997 Coll.**, on technical requirements for products and amending and supplementing certain Acts	**Section 2**
Act No. **90/2016 Coll.** on the conformity assessment of specified products when placed on the market	**Section 2**

Specific terminology for individual **product sectors** is then set out in the relevant EU and Czech legislation. For example, for construction products under Regulation (EU) No **2024/3110 of** the European Parliament and of the Council, this is set out in **Article 3** of that Regulation.

2. Basic principles for placing products on the EU/Czech market

In the Czech Republic, products are divided into **'specified products**', which are subject to stricter criteria and conformity assessment procedures (the regulated sector), and products that do not fall within this category and need only comply with general safety principles.

So-called **'specified products'** (see **the list of specified products – ÚNMZ website**)

within the Czech Republic are products that pose an increased risk to legitimate interests. These products generally fall within the scope of one of the following two Acts:

- **Act No. 22/1997 Coll.**, **on technical requirements for products and on amendments to certain acts** (as amended, including the most recent amendment by Act No. **330/2025 Coll**.), hereinafter referred to as **Act No. 22/1997 Coll.**

  Sectors covered by Act No. 22/2016 Coll. – harmonised area (NA)

  Selected products covered by Act No. 22/1997 Coll. – non-harmonised area

- **Act No. 90/2016 Coll. on the conformity assessment of specified products when placed on the market** (as amended), hereinafter referred to as **Act No. 90/2016 Coll.**

Sectors covered by Act No. 90/2016 Coll. – harmonised area (NLF)

*Note 1: **A draft Act** amending **Act No. 22/1997 Coll**. and **Act No. 90/2016 Coll.** is now ready. It is being submitted in order to adapt to Regulation (EU) 2024/3110 of the European Parliament and of the Council, which lays down harmonised rules for the placing of construction products on the market and repeals Regulation (EU) No 305/2011.*

In addition to the regulations falling under the two Acts mentioned above, the specified products include **Batteries and waste batteries (NLF), Artificial intelligence (NLF), Packaging and packaging waste (NLF) and Pyrotechnic products.**

In the EU**,** the free movement of goods is based on **the harmonisation of Member States' legislation,** which is divided into harmonisation regulations under **the New Approach (NA) and** harmonisation regulations under **the New Legislative Framework (NLF).**

EU harmonisation regulations under the New Approach (NA)

In 1985, the so-called **'New Approach to technical harmonisation and standards' (New Approach – NA**) was established. Its fundamental principle is to define the role of European Community directives, which have since been limited to requirements for products solely in terms of their safety, the protection of human health and property, and the protection of the environment (i.e. in terms of legitimate interests). It was on this principle that **the** so-called **New Approach Directives** were first drawn up. New Approach Directives, which cover key product sectors, must be fully transposed into national legislation (e.g. Czech Government Regulations) and are legally binding documents. Where harmonised technical requirements for certain products are set out in a European legal act in the form **of an (EU) Regulation,** that act must be applied directly in an EU Member State and is not transposed into a Czech Government Regulation (e.g. Regulation (EU) No 305/2011 of the European Parliament and of the Council on construction products); only, for example, the competences of national authorities are set out in the overarching legislation, which in the Czech Republic is **Act No. 22/1997 Coll.**

The New Approach to technical harmonisation is not applied universally; the old, sector-specific approach to technical harmonisation is still maintained for certain selected types of products, particularly foodstuffs, medicinal products and other products that may pose a heightened risk to health and safety (e.g. motor vehicles, etc.).

However, the New Approach Directives and Regulations contain only the essential requirements necessary to ensure product safety, the protection of health, property and the environment. Detailed technical specifications of these requirements are then set out in harmonised technical specifications, which primarily include **harmonised standards**. As a general rule, compliance with the requirements of harmonised standards implies compliance with the requirements of the New Approach Directives or Regulations (EU) (harmonisation legislation). Gradually, further principles of testing and certification have been incorporated into these New Approach Directives and Regulations, in particular elements that ensure the credibility of the system and are a prerequisite for the recognition of certificates amongst Member States. At the same time, a system of assessment procedures has been adopted which can be used to assess the conformity of products, as well as rules for affixing and using the CE conformity marking.

EU harmonisation regulations under the so-called **'New** Approach' **(New Approach – NA)** are covered in Czech legislation **by Act No**. **22/1997 Coll.**, and include the following product sectors (for each sector, the relevant EC/EU/Czech regulations and harmonised standards, where issued, can be accessed; see also **Annex 1** for an overview):

Sectors covered by Act No. 22/2016 Coll. – harmonised area (NA)

EU harmonisation regulations under the New Legislative Framework (NLF)

The EU **'New** Approach' harmonisation regulations are currently being revised, supplemented and replaced by directives or (EU) regulations under **the 'New Legislative Framework**' **(NLF)**; detailed information on NLF documents is provided in **Chapter 3** of this publication.

The principles of the NLF have been transposed in the Czech Republic into **Act No. 90/2016 Coll.** This Act covers the following harmonised product sectors, which have already been addressed in accordance with the NLF (for each sector, it is possible to access the relevant EU/Czech regulations and harmonised standards, where these have been issued):

Sectors covered by Act No. 90/2016 Coll. – harmonised area (NLF)

In addition to the sectors covered by Act No. 90/2016 Coll., the NLF also includes the following specified products : **),** : **Artificial intelligence (NLF),** : **Packaging and packaging waste (NLF).**

Selected products – non-harmonised area

This is the part of the regulated area where EU harmonisation has not taken place, so national regulations apply here.

In the Czech Republic**,** the following regulations for **selected products** fall within this non-harmonised area under **Act No**. **22/1997 Coll.:**

- **Government Regulation No. 163/2002 Coll., laying down technical requirements for selected construction products** (as amended), and **Government Regulation No. 173/1997 Coll.**
- **Government Regulation No. 173/1997 Coll., laying down selected products subject to conformity assessment** (as amended), and **Government Regulation No. 173/1997 Coll.**
- **Selected nuclear power plant equipment** under Act No. **263/2016 Coll.** (the Atomic Act and its implementing regulations).

3. New Legislative Framework (NLF)

On 1 January 2010*,* the **New Legislative Framework** (**NLF***)* came into force*.* It is a set of European Union rules designed to harmonise the legal framework governing the placing of products on the market within the EU's internal market. Its aim is to improve the functioning of

the EU's internal market for goods, to clarify the obligations of economic operators and conformity assessment procedures, including obligations relating to marking (e.g. CE), etc. It helps to ensure that products meet essential safety and technical requirements before they are placed on the market. It simplifies the rules for businesses operating in several Member States, including those relating to **mutual recognition.**

The **New** Legislative **Framework** (NLF) provides a framework for **regulations and standards in harmonised areas – sectors covered by Act No. 90/2016 Coll.**, as well as for **batteries and waste batteries, Artificial Intelligence (NLF), Packaging and packaging waste (NLF)** (for regulations drawn up in accordance with the NLF, see also **Annex 2** of this publication).

Harmonised standards for the NLF and management systems have also been published in the Official Journal of the EU; see the current overview:

Harmonised standards for the new legislative framework and management systems

The NLF consists of the following three horizontal documents:

a) Common Framework

Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (as corrected on 1 July 2015).
This document sets out common principles for the revision or recasting of New Approach Directives.

> *The Blue Guide 2022 (+ corrigendum of 24 September 2026) (English: Blue Guide 2022, + corrigendum of 24 September2026) serves as a guide for the implementation of European documents based on the New Legislative Framework. This guide follows on from the 2000, 2014 and 2016 editions. It is intended solely as a guidance document; only the text of the individual EU harmonisation acts has legal force.*
>
> *Certain principles of Decision No 768/2008/EC of the European Parliament and of the Council are also beginning to be applied in other EU harmonisation legislation that does not relate to the placing of products on the market, such as **environmental protection, ecodesign, artificial intelligence, sustainability**, etc.*

b) Requirements for accreditation and market surveillance

Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, as corrected on 3 July 2015 (consolidated version).

> *The following has been adopted in relation to this Regulation:*
>
> - *Commission Implementing Decision (EU) 2024/581 on a harmonised standard for the accreditation of medical laboratories in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council*

This Regulation is directly applicable in the Member States and lays down:

- **rules on accreditation;**
- **rules on market surveillance;**
- **rules on checks on products from third countries;**
- **rules on CE marking.**

c) Mutual recognition under the NLF

Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully placed on the market in another Member State and repealing Regulation (EC) No 764/2008.

This Regulation provides that importers are not required to carry out conformity assessments, issue declarations of conformity, draw up declarations of performance, affix the conformity marking to products, or keep records of conformity assessments for those products for which a conformity assessment has been carried out in accordance with the relevant technical regulations in the manufacturer's Member State. Under this Regulation, the manufacturer, importer, distributor or authorised representative may draw up **a** so-called **declaration of mutual recognition** (a model is set out in the Annex to this Regulation).

> *Details regarding the declaration of mutual recognition are set out in a document published in the Official Journal of the EU, Series C: Guidelines on the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully placed on the market in another Member State*

A public consultation on the NLF is currently underway:

Product legislation – ensuring timeless rules (revision of the NLF)

The final summary report has been published here**.**

4. General safety

As a general rule, all products (including construction products) must be safe, and the manufacturer is liable for damage caused by a defect in the product.

The fundamental directly applicable regulation governing safety requirements for consumer products in the EU, including the Czech Republic, is Regulation **(EU) 2023/988 on general product safety**, amending Regulation (EU) No (EU) 1025/2012 and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (consolidated version).

This Regulation also repeals Directive 2001/95/EC with effect from 13 December 2024. During the transitional period (from 12 June 2023 to 12 December 2024), it was possible to place on the market products covered by Directive 2001/95/EC. With effect from 9 December 2026, Directive 85/374/EEC (as amended by Directive 1999/34/EC) on **liability for defective products** is repealed and will be replaced by Directive (**EU) 2024/2853** of the European Parliament and of the Council; see **Chapter 10** for details.

In the Czech Republic, the transposing legislation for this Regulation is **Act No. 387/2024 Coll. on general product safety and amending certain related acts (repealing Act No. 102/2001 Coll.,** including implementing regulations, and amending **the Consumer Protection Act and the Act on Market Surveillance of Products)**.

Safety Gate:

Regulation (EU) 2023/988 provides for the possibility for consumers and other interested parties **to notify the Commission of products that may pose a risk to the health and**

safety of consumers via a separate section of the **Safety Gate** portal (formerly the RAPEX system). To this end, Commission Implementing Regulation ( ) **(EU) 2024/1435**, laying down **a model for notifications of product recalls**, and Commission Implementing Regulation **(EU) 2024/1459** concerning the establishment of **an interoperable interface of the Safety Gate portal for online marketplace providers**, Commission Implementing Regulation **(EU) 2024/1740** concerning **the procedures** by which consumers and other interested parties inform the Commission of products that could pose a risk to the health and safety of consumers, and the procedures for forwarding such information to the relevant national authorities; and Commission Implementing Regulation **(EU) 2024/2639** laying down **implementing rules** for Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the powers and tasks of the single national contact points of the **Safety Gate** early warning system**.**

The Commission draws up and regularly updates **guidelines for the management of the early warning system**. To this end, the following two documents have recently been published:

Regulation	Title
2026/1040	EFTA Surveillance Authority Decision No 146/25/KOL of 9 September 2025 adopting guidelines for the Safety Gate early warning system established under Directive 2001/95/EC on general product safety [2026/1040]
2026/1039	EFTA Surveillance Authority Decision No 146/25/COL of 9 September 2025 adopting guidelines for the Safety Gate early warning system established pursuant to Directive 2001/95/EC on general product safety [2026/1039]

Member States must report data to the Commission concerning the application of Regulation (EU) 2023/988 of the European Parliament and of the Council using **the output indicators** set out in Commission Implementing Regulation **(EU) 2024/2958.**

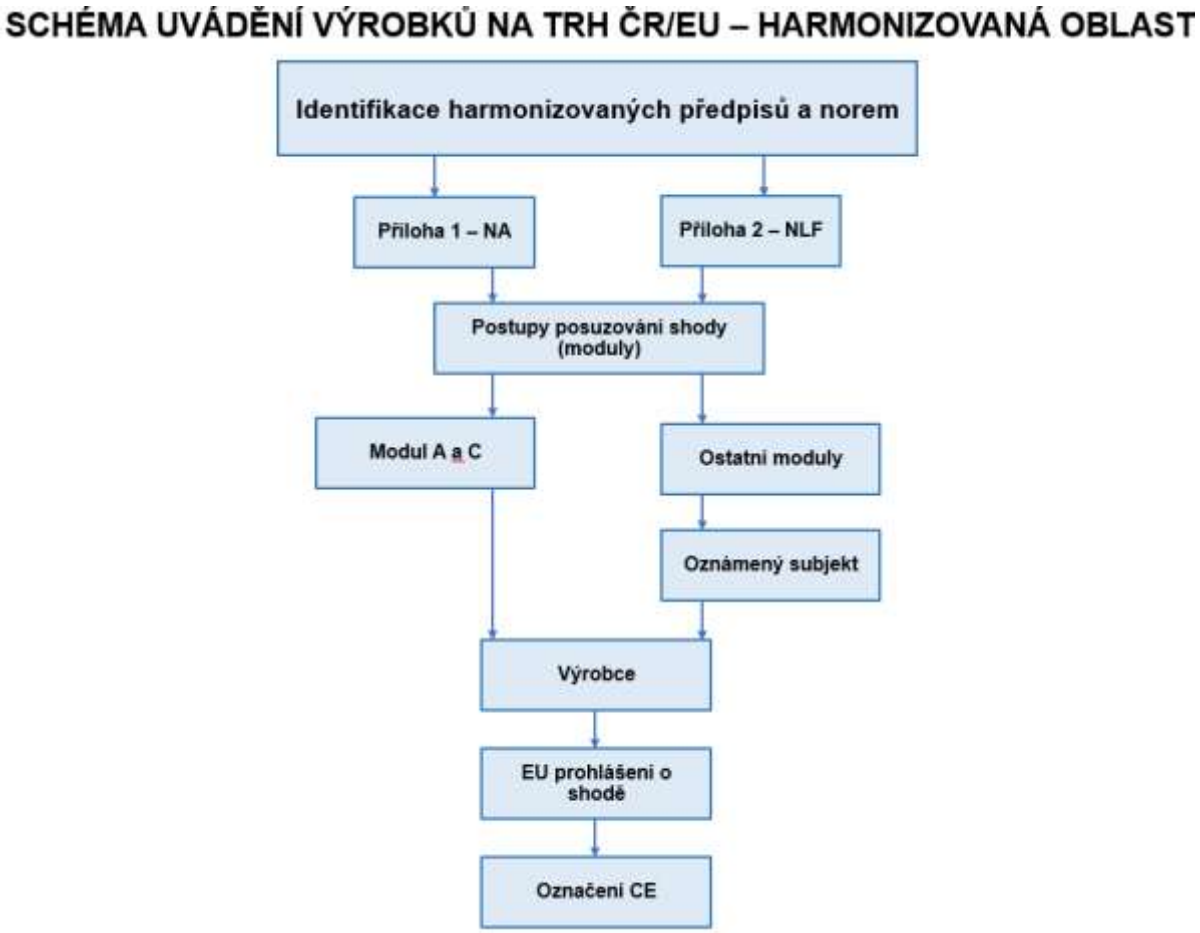
Commission Delegated Regulation (EU) **2024/3173** supplements Regulation (EU) 2023/988 of the European Parliament and of the Council (EU) 2023/988 as regards **the rules on access to** and **operation** of the **Safety Gate early warning system, the information to be entered into that system, the reporting requirements and the criteria for assessing the level of risk**.

TRIS database:

The obligation to notify draft technical regulations and standards prior to their adoption is imposed on Member States by Directive **(EU) 2015/1535** of the European Parliament and of the Council, which replaced Directive 98/34/EC with effect from 7 October 2015. These notifications are published in the **TRIS** database.

Note: As part of the Information Portal – Construction Products, the section 'Selected documents from the TRIS database for construction products' is updated monthly; these documents can serve not only as a guide when placing construction products on the market of another Member State, but also as inspiration when drafting technical regulations.

5. Procedure for placing products on the market – harmonised area



Key:

Annex 1 – Harmonised regulations and harmonised standards according to the NA

Annex 2 – Harmonised regulations and harmonised standards under the NLF

Specific features of construction products: *In the case of construction products, modules are not used; instead, systems* ***1+, 1, 2+, 3+, 3 and 4*** *are applied, and an 'EU Declaration of Conformity' is not issued, but rather a 'Declaration of Performance' or a 'Declaration of Performance and Conformity'*

5.1 Harmonised regulations and harmonised standards

The harmonised scope covers those products that can be classified under one of the following sectors (for each sector, the relevant regulations and harmonised standards can be accessed directly):

a) **Harmonised area NLF – sectors under Act No. 90/2016 Coll.** (**+Batteries and waste batteries, Artificial Intelligence (NLF), Packaging and packaging waste (NLF),** see also **Annex 2**)

b) Harmonised area NA – sectors under Act No. 22/1997 Coll. (**+Pyrotechnic articles**, see also **Annex 1**)

Principle: If a specified product falls within **a harmonised area,** the manufacturer draws up **an 'EU Declaration of Conformity'** and affixes **the CE marking** to the product**.**

Specifics of construction products – see the Information Portal – Construction Products:
*Under CPR-2011**, a 'Declaration of Performance'** is issued, and under CPR-2024**, a 'Declaration of Performance and Conformity'** is issued**.***

If a product falls within one of the sectors listed under point (a) or (b), the provisions of the relevant legislation must be complied with. In the case **of a Regulation (EU)**, the Czech Republic applies this European legislation directly; in the case **of a Directive**, **the** relevant **Czech Government Regulation** applies. Furthermore**, delegated acts** must be followed where these have been adopted for the relevant sector**.** References to **harmonised standards**, amongst other things, are also published in the form of delegated acts.

*The Commission may adopt **delegated acts** (also known as 'delegated and implementing acts') for the purpose of adapting to technical progress, new environmental risks and the regulatory needs of Member States. They help to ensure, in a practical manner, the uniform and effective application of EU legislation across all Member States.*

Delegated acts include:

***(a) Delegated acts** are adopted by the European Commission to supplement or amend certain non-essential elements of a legal act (such as a Regulation (EU) or a Directive).*

***b) Implementing acts** are adopted by the European Commission to ensure uniform conditions for the implementation of legally binding acts of the European Union (such as a Regulation (EU) or a Directive) in all Member States.*

The European Commission also issues interpretative documents/guidelines to support the correct application of the aforementioned legislation. Although these guidelines are not legally binding, they have been drawn up with the full consensus of all stakeholders (legislators, representatives of economic operators, administrative and supervisory authorities, etc.) and contain guidance, instructions and explanations on how to apply individual provisions of legislation in specific cases; they are widely respected across Europe and it is therefore advisable to familiarise oneself with them and make use of them.

Harmonised standards are issued for individual sectors**.**

The legal framework for the development of harmonised standards is set out in Regulation (EU) No **1025/2012 on European standardisation**, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC, and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council.

A harmonised standard is defined here as a European standard adopted at the request of the Commission for the purpose of implementing Union harmonisation legislation.

The Regulation on European standardisation is currently under review. The European Commission has presented **a proposal for a new Regulation on European standardisation**, which is intended to completely replace the existing regulation from 2012. One of the reasons for this is to shorten the lengthy process of developing harmonised standards.

Harmonised standards become binding upon publication of a reference to them in the Official Journal of the European Union (OJEU) in the form of **a Commission implementing act**. A typical harmonised standard includes the scope of the standard, normative references, terms and definitions, the required product characteristics and the methods for testing them. For the purposes of meeting the requirements of a given regulation, Annex ZA is of paramount importance, as it specifies which parts of the standard are directly relevant to conformity with that regulation. Annex ZA describes how the essential characteristics of the product are addressed and provides guidance on how to declare these characteristics.

The transitional period (period of co-existence) for a harmonised standard is a time-limited period beginning on the date of entry into force of the harmonised European standard (the standard's validity as a harmonised standard) and ending on the date by which all conflicting technical regulations must be repealed. This means that, upon the first publication of a harmonised standard in the Official Journal of the EU, there is a period during which both national technical specifications and the harmonised standard may be used in parallel for the purposes of CE marking. After this date, only the harmonised standard may be used. If a standard that was previously published as harmonised is replaced by a new revision, this means that, for the purposes of affixing the CE marking, both versions of the standard – the old and the new – may be used during the period of concurrent validity. Once the period of concurrent validity has ended, only the new standard may be used.

If a harmonised European standard has been withdrawn and replaced by a new European standard which has not yet been published in the OJEU, the withdrawn standard must be used for the purposes of demonstrating conformity and affixing the CE marking until the new EN is published in the OJEU; for further details, see:

Statement by the National Institute of Metrology (ÚNMZ) on revisions to harmonised European standards issued by CEN

Although European harmonised standards are non-binding, they must remain non-binding even when adopted into national standards. Compliance with the requirements of a harmonised standard, as set out in its Annex ZA, is deemed to constitute compliance with the relevant provisions of the European harmonisation legislation. Although these Annexes ZA are not normative but merely informative, they are binding in terms of compliance with the requirements of the relevant European harmonisation legislation, particularly with regard to the affixing of the CE marking to a product.

A single harmonised standard may be published in the OJEU in relation to several harmonisation regulations, e.g. **EN 621:2009** (CPR-2011 and GAD).

All European standards, including harmonised standards, are adopted into the ČSN. Under Act No. 22/1997 Coll. (see **Section 4a** in detail), a Czech technical standard becomes a harmonised Czech technical standard **if it fully incorporates the requirements laid down by a harmonised European standard.** It follows that, as soon as a harmonised standard that

has already been incorporated into the ČSN is newly published in the Official Journal of the European Union (OJEU), that ČSN becomes a Czech harmonised standard.

To determine whether **a harmonised standard** applies to a product in a particular sector, one can simply check **the product sector** in question. The current status of harmonised standards is listed here and is updated monthly. If it is not possible to assign a product to a specific sector with certainty, it is advisable to use **the database of all harmonised standards** to quickly determine whether a harmonised standard exists or to verify that a given standard is harmonised.

> ***Specifics of construction products – see the Information Portal – Construction Products:***
> *A specialised database of harmonised standards is now available for construction products:*
> *Database of harmonised standards for CPR-2011*
> *Database of harmonised standards for CPR-2024*
>
> *In addition to harmonised standards, a voluntary procedure for affixing the CE marking based on a European Technical Assessment (ETA) in accordance with a European Assessment Document (EAD) may also be used for construction products. These EADs can be found in the following databases:*
> *Database of European Assessment Documents relating to CPR-2011*
> *Database of European Assessment Documents for CPR-2024*

5.2 Conformity assessment procedures – harmonised area

Before the manufacturer begins testing the product, they must determine, in accordance with the relevant legislation and harmonised standards, which **conformity assessment procedure** (**Modules A to H1)** applies to their product and whether they can assess the product themselves (Modules A and C) or whether they will need to involve a third party, i.e. **a notified body**, as part of the conformity assessment (other modules). The conformity assessment also includes **technical documentation** (see **Chapter 8**) and **a risk analysis** (see **Chapter 7**).

> ***Specific features of construction products – see the Information Portal – Construction Products****:*
> *In the case of construction products, modules are not used; instead, the following systems are used:* ***1+, 1, 2+, 3+, 3 and 4****.*

5.3 Notified bodies

A notified body becomes involved in the conformity assessment process where the relevant conformity assessment system requires the involvement of a third party.

Notified bodies are legal entities carrying out conformity assessment that have been officially designated and notified by their national notifying authority. This is a service in the public interest provided to manufacturers anywhere in the world.

The NANDO (New Approach Notified and Designated Organisations) **information system database** allows users to search for the required notified body by country, directive, EU regulation and other criteria.

This database forms part of **the SMCS (Single Market Compliance Space),** i.e. a portal bringing together databases and information on notified bodies (NANDO), market surveillance (ICSMS) and noise emissions (Noise). Hereinafter referred to as **SMCS/NANDO**.

In the Czech Republic, the following can be used for searches:

- **the list of Czech notified bodies in SMCS/NANDO** (including their areas of competence)
- **the list of Czech notified bodies on the ÚNMZ website**
- **list of AAAO members and their websites** (though not all Czech notified bodies are members of the AAAO)

To fulfil the requirement for the mandatory involvement of a notified body in the conformity assessment, the manufacturer may choose from among those notified bodies that are notified for the relevant standard, product and module. There are usually several such bodies available for a single standard. The scope of competence within a single standard, as well as across several different standards, varies for each notified body.

The scope of authorisation is always defined for:

- the product (group of products);
- the legal regulation, or part thereof;
- and the conformity assessment module/procedure, with any further specifications;

***Specifics of construction products – see the Information Portal – Construction Products**:*
Under CPR-2011 and CPR-2024, in addition to notified bodies, there are also so-called technical assessment bodies (TAB): Overview of Czech notified bodies and technical assessment bodies (TAB) for CPR-2011.

Notifying authorities are the bodies designated by the Member States which, pursuant to **Act No**. **22/1997 Coll.**, **Act No. 90/2016 Coll.** and **Regulation (EC) No. 765/2008 of the European Parliament and** of **the Council**, are responsible for notifying these notified bodies. A notifying authority must be established in such a way as to avoid any conflict of interest with notified bodies, and must be organised and operated in such a way as to guarantee its competence, objectivity and impartiality. In the Czech Republic, the notifying authority is **the Office for Technical Standardisation, Metrology and State Testing (ÚNMZ)**. As part of an administrative procedure, ÚNMZ assesses whether the body meets the requirements laid down in the relevant legislation and, if so, enters the notification into **the SMCS/NANDO information system** and notifies the applicant accordingly; if not, it rejects the application. If neither the European Commission nor any of the Member States of the European Union raises an objection within the specified time limit, ÚNMZ will issue a certificate of authorisation. The ÚNMZ shall subsequently publish a notice in the ÚNMZ Bulletin announcing the granting of authorisation, including the scope of the authorisation, the date from which the body may carry out the activities of a notified body, the identification number of the notified body, and the number and date of issue of the certificate of authorisation.

Applicants for notification demonstrate their professional competence to carry out conformity assessment activities, amongst other things, through their accreditation, carried out in accordance with **Regulation (EC) No 765/2008 of the European Parliament and of the Council**, as amended by **Regulation (EU) 2019/1020 of the European Parliament and of the Council.** In the Czech Republic, this is carried out by a single national accreditation body – **the Czech Accreditation Institute (ČIA).** In addition to the accreditation rules, the scope of accreditation for individual organisations can be found on the ČIA website.

Notified bodies may provide their services to manufacturers established both within and outside the EU. Conformity assessment documents, identified as the results of work carried out by bodies within the scope of their notification (including those established in the Czech Republic), are valid/applicable throughout the EU/EEA.

5.4 EU Declaration of Conformity

If the specified product falls within **a harmonised area,** the manufacturer draws up **an 'EU Declaration of Conformity'.**

The requirements for the declaration of conformity are set out for each sector in the relevant harmonised legislation.

> ***Specifics of construction products – see the Information Portal – Construction Products:***
> *In the case of construction products, a 'Declaration of Performance' (CPR-2011) or a 'Declaration of Performance and Conformity' (CPR-2024) is issued*
> *Declaration of Performance and requirements for CE marking in accordance with CPR-2011*
> *Declaration of Performance and Conformity and requirements for CE marking under CPR-2024*

Where a product is subject to more than one directive (regulation), only one declaration of conformity is issued.

By drawing up the declaration of conformity, the manufacturer accepts responsibility for the product's compliance with this declaration.

5.5 CE marking

In the Czech Republic, the obligation to affix the CE marking arises from Act No. **22/1997 Coll.** and Act No. **90/2016 Coll.**, as well as from related harmonisation regulations. Under the new horizontal legislative framework, the conditions for affixing the CE marking are set out in **Decision No. 768/2008/EC of the European Parliament and of the Council**.



Details and general principles are set out in the section **'CE Marking and Other Markings**'.

The CE marking indicates that, prior to being placed on the market, the product in question has been verified and confirmed as complying with the requirements of the relevant EU harmonisation regulations, and that it may therefore be placed on the market. The CE marking

is mandatory where required by EU harmonisation regulations. It is affixed to products placed on the market in the EEA (and Turkey), regardless of where they were manufactured.

For products assembled to their final state by the manufacturer, the CE marking is affixed by the manufacturer themselves or by their authorised representative before the product is placed on the market. For specified products assembled to their final state at the place of destination, the CE marking is affixed by the product supplier on the basis of a decision by a notified body, prior to the product being put into service.

The CE marking must be permanently affixed to the product itself, to an attached label or to the packaging. In accordance with certain harmonised regulations, the CE marking is accompanied by the identification details of the notified body involved in the conformity assessment.

Further details on the marking of a specific product are set out in the relevant EU harmonisation regulations for individual sectors (in accordance with which the conformity assessment was also carried out), although these differ from one another in their specific provisions.

The CE marking indicates that the product meets the technical requirements laid down in the relevant legislation and that the prescribed procedure has been followed.

Significant changes to the CE marking are currently being prepared in connection with the introduction of **digital product passports;** see **Chapter 12.4** for details**.**

The obligation or option to use the CE marking is also set out in other EU regulations (and the corresponding national regulations of Member States, including the Czech Republic, resulting from their transposition); however, these cannot be regarded as regulations concerning the placing of specified products on the market. The relevant rules contained in these regulations may differ from those in this publication; a list of them can be found, for example, in **'Regulations and standards for ecodesign and energy labelling of appliances**'.

6. Placing products on the market – non-harmonised area

6.1 Non-harmonised regulations and designated standards

In the Czech Republic, the specified products covered by **Act No**. **22/1997 Coll.** include the following sectors falling within the non-harmonised area:

a) **selected construction products** pursuant to Government Regulation **No. 163/2002 Coll.**
b) **selected products** pursuant to Government Regulation No. **173/1997 Coll.**
c) **Selected nuclear energy facilities** under Act No. **263/2016 Coll.** (the Atomic Act and its implementing regulations).

So-called **'designated standards'** may be issued for non-harmonised regulations relating to specified products. The following links may be used to determine whether a designated standard applies to a product:

Overview of designated ČSN standards relating to Government Regulation No. 163/2002 Coll.

Overview of designated ČSN standards relating to Government Regulation No. 173/1997 Coll.

Designated standards *are Czech technical standards, other technical standards or technical documents of international or foreign organisations, or other technical documents designated by the relevant ministries and other central administrative authorities whose remit covers the area in question. These documents contain more detailed specifications of the technical requirements for products arising from a Government Regulation or other relevant technical regulation. The ÚNMZ publishes notices of these designated standards, their amendments or their repeal in the ÚNMZ Bulletin in accordance with Section 4a of Act No. 22/1997 Coll. At the same time, it specifies the technical regulation to which these standards relate. Designated standards are not issued solely for specified products; see the Overview of all regulations and the designated standards issued in relation to them.*

6.2 Conformity assessment procedures – non-harmonised area

a) Pursuant to Government Regulation **No. 163/2002 Coll. – selected construction products**

The relevant conformity assessment procedure, i.e. **in accordance with Sections 5**, **5a**, **6**, **7** or **8**, which is specified for individual items in Annex 2 to Government Regulation No. 163/2002 Coll. Where designated **standards** exist for a construction product and these standards specify the performance characteristics in relation to **the essential requirements for construction works**, the conformity assessment shall be carried out on the basis of the designated standard. If no specified standard exists for the product, or if it does not adequately cover the necessary characteristics in relation to the essential requirements, **a technical construction certificate (STO)** is issued (pursuant to Section 3 of Government Regulation No. 163/2002 Coll.).

b) Under Government Regulation No. **173/1997 Coll. – selected products**

For products listed in Annex 2, the manufacturer, importer or distributor shall ensure that an authorised body assesses the conformity of a product sample (prototype) with the essential requirements for products.

6.3 Authorised bodies

An authorised body is a legal entity authorised by the Office for Technical Standardisation, Metrology and State Testing (ÚNMZ) to carry out activities relating to the conformity assessment of products under Act No. 22/1997 Coll. and shall carry out these activities within the scope defined in the authorisation decision. Authorised bodies are involved, for example, in the conformity assessment of selected construction products in accordance with Government Regulation No. **163/2002 Coll.** or of selected products in accordance with Government Regulation **No. 173/1997 Coll.**

List of bodies authorised to carry out conformity assessment activities for selected construction products

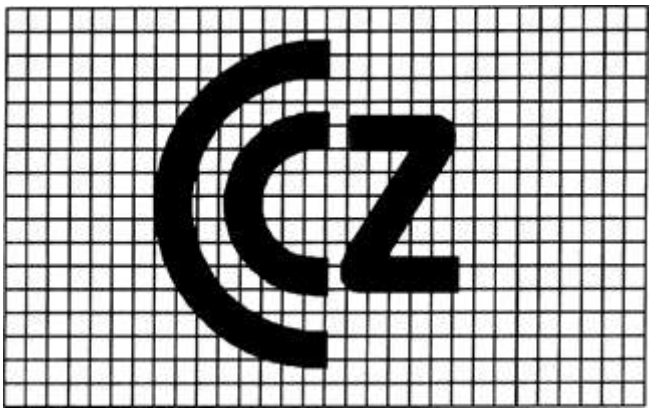
List of bodies authorised to carry out conformity assessment activities for selected products

6.4 Product marking – non-harmonised area

If the specified product falls within **a non-harmonised area** (selected construction products and selected products subject to conformity assessment), the manufacturer shall draw up **a 'Declaration of Conformity'** and, where required by the relevant regulations, affix the national conformity mark (Ccz) to the product.

E.g. in accordance with Government Regulation **No. 163/2002 Coll.**

Sample graphic design of the Czech conformity mark in accordance with Government Regulation **No. 163/2002 Coll.:**



***Specifications for construction products – see the Information Portal – Construction Products**:*

Details of Government Regulation No. 163/2002 Coll. on the placing on the market of selected construction products without the CE marking

Procedure for placing construction products on the market in accordance with Government Regulation No. 163/2002 Coll. without CE marking

Selected construction products (12 items as set out in Annex 2 to Government Regulation No. 163/2002 Coll.)

Mutual recognition – obligations of distributors placing non-harmonised construction products on the market in the Czech Republic

7. Risk analysis

7.1 Risk analysis as part of conformity assessment

Risk analysis is an important part of assessing product safety and demonstrating its conformity with the relevant legal requirements. Its purpose is to systematically identify hazards that may be associated with the product, assess the risks arising from these hazards, and determine appropriate measures to eliminate or reduce them.

In some **conformity assessment procedures** (**Modules A to H1)**, a risk analysis with regard to product safety is prescribed. However, the scope and method of documenting the risk analysis are primarily governed by the relevant legislation for the type of product in question. Some harmonised legislation for specific **product groups** expressly requires the manufacturer to include a risk analysis and assessment in the technical documentation (see **Chapter 8**). The requirements may vary depending on the specific legislation and the conformity assessment procedure used. It cannot therefore be generally assumed that a risk analysis is required only for certain conformity assessment modules.

Risk analysis and assessment are also an important part of product conformity assessment. Their performance and documentation stem from the requirements of the relevant EU harmonisation legislation. Even where a specific conformity assessment procedure does not explicitly stipulate a detailed risk analysis, carrying one out is an important tool for verifying product safety. This is also supported by the European Commission in **the Blue Guide, Chapter 5**.

Technical documentation (sometimes referred to more broadly as accompanying documentation) forms part of the conformity assessment and must, to the extent necessary, include documents sufficient to enable the conformity assessment mechanism to be carried out during the design, manufacture and operation of the product.

7.2 Identification of legislative requirements and hazards

When carrying out a risk analysis, it is first necessary to identify the legislation applicable to the product and the essential or other relevant requirements arising therefrom. Subsequently, these requirements must be applied to the specific product, in particular to its design, the materials and components used, its technical characteristics, the method of manufacture, its intended use and any reasonably foreseeable misuse.

The manufacturer or importer must ensure that the product is safe in accordance with **the binding legal regulations of the EU and the Czech Republic**.

The following regulations must be taken into account:

- **Regulation (EU) 2023/988 of the European Parliament and of the Council on General Product Safety (GPSR)**: This is a key piece of legislation directly applicable in all EU Member States from **13 December 2024**. It replaces the previous Directive 2001/95/EC. It stipulates that products placed on the market must be safe and requires economic operators (manufacturers, importers, distributors) to carry out a risk analysis to ensure compliance with safety requirements.

- **Act No. 387/2024 Coll., on General Product Safety**: This Czech Act follows on from the GPSR Regulation referred to above and governs the exercise of state administration and market surveillance in the Czech Republic. It lays down national rules for the implementation of the European Regulation.

- **EU harmonisation legislation and harmonised standards for individual product groups.**

Product safety may be governed by several pieces of legislation simultaneously, including both EU harmonisation legislation and the national legislation of Member States. When carrying out

a risk analysis, it is therefore necessary to assess all relevant legal requirements and their interaction. The fact that a particular aspect of product safety is governed by a specific piece of legislation does not preclude the need to take other related requirements into account.

Simply identifying the applicable legislation and requirements does not in itself constitute risk identification. It is necessary to assess what hazards may arise from the product's characteristics and under what circumstances they may lead to harm. Consideration is given, for example, to mechanical, electrical, thermal, chemical, fire, radiation or hygiene hazards, or hazards relating to stability, ergonomics, software or cyber security, where these are relevant to the product in question.

When identifying hazards, it is advisable to base the assessment primarily on:

- the intended use of the product and its anticipated life cycle;
- reasonably foreseeable misuse;
- persons who may come into contact with the product, including children, the elderly or persons with disabilities, where relevant to the product;
- the environment and conditions in which the product will be used, stored, transported, installed or maintained;
- possible faults, wear and tear, ageing of materials and foreseeable changes in the product's characteristics;
- experience gained from the use of similar products, complaints, accidents, incidents and test results.

Technical standards can serve as an important basis for identifying hazards and verifying compliance with safety requirements. However, it is necessary to verify whether the standard actually applies to the product in question and whether it covers all relevant hazards and aspects of its safety. Even the use of a harmonised standard does not, in itself, preclude the need to assess other risks not covered by the standard or arising from the specific design or use of a particular product.

Technical standards setting out principles, procedures or specific methods may be used in risk analysis and assessment. However, it is necessary to distinguish between standards intended specifically for the safety of a particular group of products and general standards for risk management and standards describing individual analytical methods. The following standards may be classified as general methods; see **Risk Management.**

For individual **product groups**, there are standards specifying certain safety requirements, such as

- **ČSN EN ISO 12100** Safety of machinery – General principles for design – Risk assessment and risk reduction
- **ČSN EN ISO 14971** Medical devices – Application of risk management to medical devices
- **ČSN EN 764-7** (+ Am. 1 and Am. 2) Pressure equipment – Part 7: Safety systems for non-heated pressure equipment

The various analytical methods, which are often used in combination, include:

- **FMEA (Failure Mode and Effects Analysis)**: Analysis of potential failures and their consequences. It focuses on the failure of individual components and their impact on the system.
- **HAZOP (Hazard and Operability Study)**: A systematic team-based method for identifying hazards and operability issues in complex processes, often in the chemical or energy industries.
- **Checklists**: A simple method using pre-prepared lists of potential hazards relevant to a given type of product.
- **"What-If" Analysis**: A less structured but flexible method in which the team asks questions about possible failure scenarios.

7.3 Risk Assessment

Once hazards have been identified, the risk associated with each is assessed; that is, the combination of the probability of harm occurring and the severity of that harm. When estimating probability, particular consideration must be given – depending on the nature of the product – to the likelihood of a hazardous situation arising, the likelihood of people being exposed to the hazard, and the possibility of a hazardous event occurring that leads to harm.

Severity is assessed on the basis of possible consequences, for example, the extent and nature of harm to health. The number of people who may be exposed to the hazard, and the duration or frequency of their exposure, may also be taken into account if they are relevant to the assessment in question.

Qualitative, semi-quantitative or quantitative methods may be used to determine the level of risk. In practice, risk matrices are often used, which combine the level of probability with the severity of possible consequences. The chosen method and its criteria must be appropriate to the type of product, the available information and the purpose of the assessment. The result should not be merely a numerical expression; it must be supported by a justification of the assumptions and conclusions used.

Subsequently, an assessment is made as to whether the identified risk is acceptable or whether further measures need to be taken. The acceptability criteria must be based on the relevant legal requirements, applicable technical standards and other relevant considerations. For products intended for consumers, it is also necessary to take into account the requirement that only safe products be placed on the market.

Risk analysis should begin as early as the product design and development phase. An early assessment makes it possible to take safety considerations into account when selecting design solutions, materials and components, and to avoid a situation where defects have to be rectified only once the product is complete.

7.4 Measures to eliminate hazards

If the assessment shows that the risk is unacceptable, appropriate measures must be designed and implemented. Priority is given to measures that eliminate or reduce the hazard directly at source. Only if this is not possible or is insufficient are technical control measures and information for users added.

For example, for machinery, ČSN EN ISO 12100 sets out this general risk reduction procedure:

- Safe design measures – eliminating hazards or reducing risk through appropriate design and construction, for example by changing the geometry, using safer materials or limiting energy.
- Technical control measures – for example, guards, interlocks, protective devices or other technical means that restrict access to hazardous parts or otherwise reduce the risk.
- Information on use – for example, instructions, safety guidelines, warning notices and signage that draw attention to residual risks and specify the conditions for safe use.

This hierarchy is specifically intended for machinery. For other categories of products, the relevant legislation and product standards must be followed. However, the general principle remains that safety should not be based solely on warnings and instructions if the risk can be more effectively controlled through design or technical measures.

Once measures have been implemented, it is necessary to reassess whether the risk has been eliminated or reduced to an acceptable level, and whether the measures taken have created new hazards or additional risks. A risk that remains even after measures have been implemented is referred to as a residual risk. Where necessary, the user must be informed of residual risks and must receive appropriate instructions for the safe use of the product.

7.5 Verification of the effectiveness of measures

The effectiveness of the measures taken must be verified using appropriate methods that correspond to the nature of the product and the risk being assessed. These may include, for example, technical assessments, reviews of the design, calculations, laboratory tests, functional tests, simulations or verification under operational conditions.

It is necessary to verify not only whether the measures have been correctly designed and implemented, but also whether they actually reduce the relevant risks and whether their introduction has given rise to new hazards. If the measures prove to be insufficient, they must be modified and the risk assessment repeated.

Risk analysis should not be a one-off activity carried out only before the product is placed on the market. It should be updated on an ongoing basis in the event of changes to the design, materials, manufacturing processes, intended use or other circumstances that may affect the safety of the product. Updates are also appropriate when new information is obtained regarding accidents, incidents, complaints or new risks.

7.6 Product safety throughout its service life

When carrying out a risk assessment, it is necessary to take into account not only the moment the product is placed on the market, but also its expected service life and any changes that may occur during use. Product safety may be progressively affected, for example, by wear and tear, ageing of materials, corrosion, degradation of electrical insulation, damage to seals, loosening of joints or a reduction in the effectiveness of protective and safety features.

The manufacturer should therefore determine, depending on the nature of the product, whether instructions are required for regular inspections, maintenance, cleaning, replacement of wear parts or other actions necessary to maintain safety. Where relevant, this information must be included in the instructions for use or in other documentation supplied with the product.

It is also advisable to take into account the foreseeable consequences of improper maintenance, the use of unsuitable spare parts, or operation beyond the expected service life. However, the safety of a product throughout its service life cannot be ensured by user instructions alone; a safe design and appropriate structural and protective measures are fundamental prerequisites.

8. Technical documentation

Technical documentation (sometimes referred to more broadly as accompanying documentation) forms part of the conformity assessment and must, to the extent necessary, include documents within the scope of that enable the conformity assessment mechanism to be carried out during the design, manufacture and operation of the product.

The scope of the technical documentation may vary across different product sectors; however, it is considered that it must, as a minimum, contain:

- a complete technical drawing of the product, including sub-assemblies, or, where applicable, diagrams of individual circuits or detailed drawings, supplemented by calculations, test results, etc., which are necessary for verifying the product's conformity in the relevant area and for demonstrating compliance with the essential general health and safety requirements;
- a list of the essential requirements for this product, the technical standards or other technical specifications used in the design of the product;
- **a risk analysis** (see **Chapter 7**) taking into account the effects of the product in the context of its use and its impact on users;
- a summary and description of the methods identified and adopted to eliminate the hazards identified on the basis of the risk analysis carried out;
- other technical assessments or certificates;
- technical reports containing the results of supplementary tests carried out at the manufacturer's own discretion or by another authorised body (laboratory), where the manufacturer declares conformity with the relevant standard in the harmonised area;
- instructions for use of the product, including, amongst other things, a description of the circumstances relating to its packaging, transport, maintenance, disposal, etc.

The obligation to prepare the accompanying documentation lies with the entity placing the product on the market.

Together with other relevant product documents (including the EC Declaration of Conformity, etc.) the accompanying documentation must be retained for inspection purposes for a period of at least 10 years, starting from the date of manufacture of the last product to which the documents relate (in the case of series production), and this important obligation must be assumed by the entity placing the product on the market even if neither the manufacturer nor the authorised representative is established in the EC.

9. Obligations of economic operators and their monitoring by market surveillance authorities

Every economic operator (**manufacturer**, their **authorised representative**, **importer**, **distributor, fulfilment service provider, etc.)** is obliged, within the scope of their role in the

supply chain, to ensure that the basic rules governing the placing of a product on the market (and into service – e.g. lifts) and its distribution are complied with.

In general, the obligations of economic operators are set out in **Decision No 768/2008/EC of the European Parliament and of the Council** (the NLF document; for details, see **Chapter 2).** Where specific sectoral regulations set out details, differences or additions to this NLF document, those regulations shall always take precedence. Direct application of the NLF document without reference to applicable and effective sector-specific regulations **is not permitted**.

This topic is discussed in more detail here: **Obligations of economic operators.**

Market surveillance is also important for economic operators as it helps to prevent unfair competition. Each Member State within the EU is obliged to designate or establish a market surveillance authority. These authorities must have the necessary resources and powers to carry out market surveillance; they must ensure the technical competence and professional integrity of their staff; and they must act independently and non-discriminatorily, whilst respecting the principle of proportionality. Notified bodies must not, as a matter of principle, be responsible for carrying out market surveillance, as this prevents conflicts of interest. The horizontal European legislation governing market surveillance is **Regulation (EC) No 765/2008 of the European Parliament and of the Council** (NLF document; see **Chapter 2** for details**).**

The manufacturer or importer must keep the relevant conformity assessment documents and make them available to the supervisory authorities for a period of 10 years from the date on which production, import or placing on the market ceased, unless otherwise specified in sector-specific legislation.

The rules on market surveillance are set out in Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance (unamended version No (EU) 2025/14, No (EU) 2025/40) and on the conformity of products with regulations, and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (the Conformity and Market Surveillance Regulation).

A public consultation on this Regulation is currently underway:

Market surveillance and product compliance – evaluation and possible revision of Regulation (EU) 2019/1020

This Regulation is transposed into Czech law by Act No. **87/2023 Coll.** (as amended by Act No. **387/2024 Coll.**) **on market surveillance of products and amending certain related acts (the Act on Market Surveillance of Products)**.

This topic is covered in detail here: **Market Surveillance Regulations**

The new legislative framework, see **Chapter 3,** and in the Czech Republic Act No. **90/2016 Coll.,** also sets out in more detail the requirements for **product traceability,** which enables **supervisory authorities** to trace a product's history. The requirements for product traceability are, in particular:

- product labelling;
- identification of economic operators in the supply chain; - retention of technical documentation.
- Economic operators are, amongst other things, obliged, for a specified period and at the request of the supervisory authorities, **to identify** all economic operators:

a) who supplied them with the product in question (their suppliers) and/or
b) to whom they supplied the product in question (their customers).

Further significant changes are in the pipeline in connection with the introduction of **digital product passports;** see **Chapter 12.4** for details.

10. Liability for defective products

The rights and obligations are set out in Directive **85/374/EEC** (as amended by Directive 1999/34/EC) **on liability for defective products.** This Directive is **repealed with effect from 9 December 2026.** However, it shall continue to apply to products placed on the market or put into service before that date.

This Directive is replaced, with effect from 9 December 2026, by Directive (EU) 2024/2853 of the European Parliament and of the Council (EU) **2024/2853** of 23 October 2024 **on liability for defective products and repealing Council Directive 85/374/EEC** (consolidated version including **Corrigendum 2026/90364)** on the definition of the right to compensation for damage caused by a defective product. A product is considered defective if it does not provide the level of safety that a person is entitled to expect or that is required by EU or national law. The manufacturer's liability also extends to the components of an individual product. The Directive further sets out provisions concerning the exemption from liability.

Damage caused by a product defect is dealt with in the Czech Republic under **Section 2939 of Act No. 89/2012 Coll. (Civil Code)**, as amended, including the latest amendment No. **333/2025 Coll**., which comes into force on 1 January 2026. **A draft bill** is currently being prepared **to amend Act No. 89/2012 Coll., the Civil Code** (implementation of Directive **2024/2853).**

11. Voluntary testing beyond mandatory requirements – for better market positioning

The professional competence and range of services offered by notified bodies are generally broader than their remit as notified bodies. This is demonstrated, amongst other things, by accreditation, a long-standing tradition, customer references, membership of international associations of similar bodies, a leading role in standardisation activities, etc. This is a prerequisite for using the same body for non-mandatory testing, inspections and certification. Through these, for example, a manufacturer demonstrates compliance with regulatory requirements where the involvement of a notified body is not mandatory. Furthermore, a manufacturer can use them to demonstrate to its customers the characteristics of its products, the reliability of its procedures, etc., even beyond the obligations arising from regulations. These activities also include, for example, the certification of management systems in accordance with the ISO 9000, 14000 series of standards, etc. Updated **lists of standards** in this field can be found here:

Management systems

For products already bearing the CE marking**,** additional **voluntary marks** may be developed, both for specified products and for construction products**.** In this context, it should be noted that any additional information accompanying the product which does not relate to harmonised aspects must be clearly separated from the information accompanying the CE marking.

The manufacturer may affix further voluntary quality marks to the product, but only in a manner that does not reduce the visibility and legibility of the CE marking, and such non-harmonised aspects must not be confused with the harmonised ones. For example, for commercial reasons, the manufacturer may go beyond the requirements of the harmonised standard and have the product certified by a notified body, even though the harmonised standard only requires an assessment by the manufacturer itself, and may subsequently affix the relevant marking to the product.

A pictogram or any other mark, in particular one indicating a specific risk or use, may be affixed alongside the CE marking.

A voluntary product certificate enhances the product's credibility, guarantees the consistency of selected product characteristics, improves the product's competitiveness, raises the product's profile and reduces the likelihood of complaints. In addition to risk analysis, testing in an accredited laboratory and comparing the product's properties with the requirements of the relevant regulations, it usually also involves monitoring the quality stability of the certified product throughout the certificate's period of validity. The certification process is often concluded with the granting of a licence to use a specific certification mark.

12. Other products to which harmonised standards apply, but which are not included amongst the specified products

In addition to the harmonisation documents described above, which are set out in detail in **Chapter 5** and in **Annexes 1** and **2**, there are several other harmonisation documents within the EU; see **Annex 3.**

There are also **harmonisation regulations and standards for ecodesign and ecolabelling**; for details, see **Chapter 13.1** of this publication.

However, many other sectors, such as **the food industry**, **the automotive industry**, **chemicals**, **pharmaceuticals**, etc.**,** do not fall within the scope of **the specified products** and are regulated within the EU by so-called sectoral directives (sometimes referred to as 'old approach directives') or by regulations and other legislation. These regulations apply to narrow categories of products, are highly detailed and also contain technical requirements and limit values. However, they do not fall within the harmonised scope and no harmonised standards are published for them.

Other products which do not pose a threat to legitimate interests and to which neither harmonisation documents nor 'old approach directives' apply fall within **the** so-called **unregulated sphere**; for these, it is necessary to comply primarily **with general safety** requirements and, furthermore, **with market surveillance regulations.**

13. Ecodesign of sustainable products

The harmonisation legislation is Regulation **(EU) 2024/1781 of** the European Parliament and of the Council **establishing a framework for setting ecodesign requirements for sustainable products**, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542, and repealing Directive 2009/125/EC (**corrections** published**: 2024/90493 and 2025/90356, 2026/90072 of 4 February 2026,** repeals Directive **2009/125/EC** with effect from 18 July 2024;

for exemptions, see Article 79) **– the ESPR (Ecodesign for Sustainable Products Regulation).**

13.1 Ecodesign and energy labels for appliances

The overarching document is Regulation **(EU) 2024/1781** of the European Parliament and of the Council **(the ESPR)**.

In the Czech Republic, Decree No. **319/2019 Coll. on energy labelling and the ecodesign** of energy-related **products** (implementing Directive 2009/125/EC) remains in force for the time being. This Decree is an implementing regulation under Act No. **406/2000 Coll. on energy management** (as amended).

A draft bill is currently being prepared in the Czech Republic **on the ecodesign of products and the exercise of state administration in this area, and on amendments to related legislation;** this has been drawn up in response to the obligation to ensure the transposition of national law into the Regulation on the ecodesign of sustainable products.

For further regulations and lists of harmonised standards, see:

Regulations and standards for ecodesign and energy labels for appliances

13.2 Repairability of products:

This is based on **Directive (EU) 2024/1799 on common rules to promote the repair of goods**. The aim of this legislation is to help consumers find repair shops by creating a common online platform for repairs, which should be operational by 1 January 2028. Annex II to Directive (EU) 2024/1799 sets out a list of Union legal acts laying down requirements for reparability, which are consistent with **the** above-mentioned **ecodesign regulations**.

The Directive must be transposed into national law by 31 July 2026. In this context, **a draft law** is currently being prepared **on certain obligations relating to the repair of products and amending Act No. 634/1992 Coll., on consumer protection.** In the Czech Republic, the joint online platform for repairs is to be administered by the Ministry of Industry and Trade.

13.3 Unsold products

Regulations governing unsold products in the EU are governed by Regulation **(EU) 2024/1781** of the European Parliament and of the Council **(the ESPR Ecodesign Regulation)**. From July 2026, large companies will be prohibited from destroying unsold clothing, accessories and footwear. Companies must prioritise selling these items, offering them at a discount, donating them to charities or recycling them. Disposal is permitted only for damaged or hazardous items. Article 25(5) of Regulation (EU) 2024/1781 sets out legitimate grounds for the destruction of unsold consumer products. These grounds include concerns

To this end, **Commission Implementing Regulation (EU) 2026/2** of 9 February 2026 was adopted**,** laying **down implementing rules for Regulation (EU) 2024/1781 of the European Parliament and of the Council as regards the details and format for the publication of information on discarded unsold consumer products**

This imposes obligations on large enterprises:

a) **prohibition on disposal:** i.e. a ban on landfilling and incineration of unsold textiles and footwear (Exceptions to the disposal ban: Only goods that are defective, pose a health risk, are counterfeit or have been rejected by a charity may be destroyed;
b) **alternative use:** e.g. the obligation to offer goods for sale at a reduced price or to donate them to charitable organisations;
c) **transparency**: companies must publicly disclose the quantities and weights of unsold products that have been discarded;
d) **data retention:** records must be kept for five years for the purposes of official inspections.

The ban applies to large enterprises with more than 250 employees and an annual turnover exceeding 50 million euros (approximately 1.2 billion crowns). Companies must now find a way to deal with goods that they previously disposed of.

Companies will only be able to dispose of unsold goods if they are hazardous, damaged or counterfeit, or if they are rejected by charitable organisations. The measure, which the EU approved more than two years ago, will also be extended to medium-sized enterprises in 2030.

13.4 Digital Product Passport (DPP)

Regulation **(EU) 2024/1781 of the European** Parliament and of the Council **(the ESPR Ecodesign Regulation)** lays down an obligation to provide products covered by the relevant sector-specific Commission regulations (delegated acts) with **a so-called digital product passport**. This should contain **all relevant data relating to the product** and be **accessible via a single data carrier**, e.g. a QR code, **throughout the product's entire life cycle**.

The mandatory **content** of the digital passport will always be defined **in the relevant Commission regulation** relating to a specific product category. Generally speaking, this will comprise **data intended for**:

- **consumers**, such as instructions for installation, use, maintenance or repairs; information on the product's energy efficiency class or concerning substances of concern; relevant labels; or information on how to dispose of the product at the end of its life;
- **repair centres or recycling organisations**, such as information on the reuse of the product, refurbishment or recycling options;
- **to supervisory authorities**, such as technical documentation, declarations of conformity, etc.

Access to individual sets of information should, however, be restricted by access rights to be determined by the digital passport administrator.

To ensure **the availability of the digital passport throughout the product's life cycle**, **a backup copy** of the passport will have to be stored with an independent entity, known as **a provider of services relating to the product's digital passport**. These entities may also be entrusted with the entire management of the product's digital passport if the economic operator does not wish to manage it themselves for any reason.

The digital product passport will be introduced **gradually for individual product categories** in parallel with the adoption of sector-specific ecodesign requirements. The digital passport will first become mandatory for certain types of batteries, with effect from 18 February 2027. The Commission is therefore already working on a regulation that will set out the requirements for entities acting as the aforementioned providers of services relating to the digital product passport.

Digital Product Passport Register:

On 20 July 2026, the European Commission launched the Digital Product Passport (DPP) register, including a test environment for users. The register does not store the full content of digital product passports, but primarily unique identifiers and registration details. The DPP data itself remains with economic operators or their service providers.

To this end, **Commission Implementing Regulation (EU) 2026/1778** of 16 July 2026 was adopted, **laying down implementing measures for the Digital Product Passport Register established under Regulation (EU) 2024/1781 of the European Parliament and of the Council.**

Information about the register and access to the DPP register is available at:

https://single-market-economy.ec.europa.eu/single-market/digital-product-passport/dpp-registry_en.

Although the first registration obligation will not come into force until **18 February 2027**, and will apply only to certain batteries under Regulation (EU) 2023/1542, the register's test environment is already available to all economic operators who meet the conditions for access to the system.

At the same time, **Commission Implementing Decision (EU) 2026/1736** of 14 July 2026 **on harmonised standards for digital product passports, drawn up in support of Regulation (EU) 2024/1781 of the European Parliament and of the Council,** has been published**.**

For further information, see: **Digital Product Passport – rules for service providers**

Specifics of construction products – see the Information Portal – Construction Products:
CPR-2024 already contains information on the digital passport; see Digital Product Passport (DPP) under CPR-2024

14. End-of-life products

End-of-life products are defined by **Act No. 542/2020 Coll**. as selected products that have served their purpose, have become waste, and for which manufacturers are obliged to ensure, at their own expense, their take-back, recycling or environmentally sound disposal.

Main product groups:

- **Electrical equipment:** Household appliances, computers, lighting fittings and telephones.
- **Batteries and accumulators:** Portable, industrial and automotive types.
- **Tyres:** Used vehicle tyres.
- **Selected motor vehicles and end-of-life vehicles**.
- **Producer responsibility:** Manufacturers and importers must fund the collection and treatment of these products.

Citizens' obligations: Users must not dispose of these products in ordinary rubbish bins, but must hand them in at recycling centres, shops or collection points.

Collective schemes: Companies often fulfil their obligations collectively through organisations that arrange for recycling.

A draft bill is being prepared **to amend Act No. 542/2020 Coll., on end-of-life products**, as amended (adaptation to Regulation (EU) (EU) 2023/1542 of 12 July 2023 on batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020, and repealing Directive 2006/66/EC).

15. Harmonised rules for the placing on the market of certain artificial intelligence (AI) systems

The framework legislation is Regulation (EU) (EU) **2024/1689** of 13 June 2024, **laying down harmonised rules on artificial intelligence** and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144, and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 **(Artificial Intelligence Act, + Corrigendum 2026/90258 of 27 March 2026, + Regulation (EU) 2026/1744 of the European Parliament and of the Council).**

The aim of Regulation (EU) 2024/1689 of the European Parliament and of the Council (EU) **2024/1689,** referred to as **the Artificial Intelligence Act (AI Act),** is to promote the development and use of safe and trustworthy artificial intelligence (AI) systems within the European Union's (EU) single market, in both the private and public sectors, whilst ensuring the protection of the health and safety of EU citizens and respect for fundamental rights. The Regulation classifies AI systems according to their level of risk. It prohibits certain particularly dangerous practices and sets out requirements for risk management, data quality, technical documentation, human oversight, accuracy and cybersecurity. The Regulation establishes rules based on risk assessment for:

- the placing on the market, putting into service and use of certain AI systems,
- the prohibition of certain AI practices,
- requirements for high-risk AI systems and related obligations,
- transparency for certain AI systems,
- transparency and risk management for general-purpose AI models (powerful AI models that support AI systems capable of performing a wide range of tasks),
- market monitoring, market supervision and governance, and the enforcement of this Regulation,
- support for innovation, with a focus on small and medium-sized enterprises (SMEs) and start-ups.

The aim **of** Regulation (**EU) 2026/1744** of the European Parliament and of the Council of 8 July 2026, **amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards simplifying the implementation of harmonised rules on artificial intelligence (the comprehensive digital package on artificial intelligence**, referred to as **the Digital Omnibus for Artificial Intelligence**), is to simplify and harmonise the application of AI rules, limit overlaps with sector-specific regulations and reduce the administrative burden. It postpones the applicability of the requirements for high-risk AI systems to 2 December 2027

for stand-alone products and to 2 August 2028 for systems embedded in products. At the same time, it amends the rules governing the AI Office and the transparency of generated content. **An opinion** on this Regulation was issued by the European Economic and Social Committee

For further information, see: **Rules for trustworthy artificial intelligence in the EU.**

A draft Artificial Intelligence Act is currently being prepared**.** The proposed legislation is an adaptation to Regulation (EU) 2024/1689 of the European Parliament and of the Council (the Artificial Intelligence Act). Its aim is to ensure the proper and timely implementation of the Artificial Intelligence Act, in particular by establishing a supervisory mechanism, including cooperation between supervisory authorities, and designating a notifying authority. A new Act regulating artificial intelligence is being introduced, which complements European rules and governs the oversight and accountability of high-risk systems.

On 12 October 2026, **Commission Implementing Decision (EU) 2026/2274 on harmonised standards for high-risk AI systems, drawn up in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council,** was published in the Official Journal of the European Union (OJEU).

The first harmonised standard, EN 18286:2026, has been published here**: Artificial Intelligence – Quality Management System for regulatory purposes under the EU Artificial Intelligence Act;** see also the ÚNMZ website**: Harmonised rules for artificial intelligence**

Thanks to this harmonised standard, providers of high-risk AI systems who comply with it can automatically gain legal certainty that their quality management system meets the strict requirements of Article 17 of Regulation **2024/1689.**

The decision represents a major milestone for the practical enforcement of European AI rules, as it provides developers with clear guidance on how to proceed before placing high-risk applications on the EU market.

16. Abbreviations

Abbreviation	English	Czech
AI Act	Artificial Intelligence Act	Artificial Intelligence Act
CE	(from French: Conformité européenne – CE marking)	(European conformity – CE marking)
CEN	Comité Européen de Normalisation (European Committee for Standardisation)	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation (Comité Européen de Normalisation de l'Electricité)	European Committee for Electrotechnical Standardisation
CPR-2011	Construction Products Regulation (EU) 305/2011	Construction Products Regulation (EU) 305/2011
CPR-2014	Construction Products Regulation (EU) 2024/3110	Construction Products Regulation (EU) 2024/3110
DPP	Digital Product Passport	Digital Product Passport
EAD	European Assessment Document (CPR)	European Assessment Document (CPR)

Abbreviation	English	Czech
EC	European Communities European Commission	European Communities (comprising the EC, EFTA and Euratom) European Commission (EC)
EEA	European Economic Area	European Economic Area (EEA)
EEC	European Economic Community	European Economic Community (EEC)
EFTA	European Free Trade Association	European Free Trade Association (EFTA)
ECHA	European Chemicals Agency	European Chemicals Agency
EIA	Environmental Impact Assessment	environmental impact assessment
EN	European standard	European standard
EOTA	European Organisation for Technical Approvals (Article 9(2) of the CPD) European Organisation for Technical Assessment (Article 31 of the CPR – Organisation of TABs)	European Organisation for Technical Approvals (Article 9(2) of the CPD) European Organisation for Technical Assessment (Article 31 of the CPR – Organisation of TABs)
EP	European Parliament	European Parliament
ESPR	Ecodesign for Sustainable Products Regulation	Regulation on Ecodesign for Sustainable Products (officially Regulation (EU) 2024/1781 of the European Parliament and of the Council)
ETA	European Technical Approval (CPD) European Technical Assessment (CPR)	European Technical Approval (CPD) European Technical Assessment (CPR)
EU	European Union	European Union
hEN	harmonised European standard (for a construction product to enable CE marking)	harmonised European standard (for a construction product – enabling CE marking)
ISO	International Standards Organisation	International Organisation for Standardisation
MS	Member State	Member State
NA	New Approach to Technical Harmonisation	New Approach to Technical Harmonisation
SMCS/NANDO	New Approach Notified and Designated Organisations (Information System)	Database of notified and designated organisations under the New Approach (information system)
NB	Notified Body (i.e. certification, inspection or testing bodies)	Notified Body (i.e. certification, inspection or testing bodies under the CPR) In the Czech translation of the CPR, this is referred to as an ‘oznámený subjekt’ (OS)
NLF	New Legislative Framework	New Legislative Framework
OJEU	Official Journal of the European Union	Official Journal of the European Union

Abbreviation	English	Czech
RAPEX	Rapid Alert System for non-food consumer products	system for the rapid exchange of information on dangerous products
REACH	Registration, Evaluation and Authorisation of Chemicals	registration, evaluation, authorisation and restriction of chemical substances
SOLVIT	Effective problem-solving in Europe	a system for the effective resolution of problems arising from the incorrect application of EU law
SVHC	Substances of Very High Concern	substances of very high concern
SVOC	Semivolatile Organic Compounds	semi-volatile organic compounds
TAB	Technical Assessment Body (CPR)	Technical Assessment Body (CPR)
TRIS	Technical Regulation Information System	Technical Regulation Information System
ZA	Annex ZA to hEN	Annex ZA to the harmonised standard

b) Czech abbreviations

Abbreviation	Name
AAAO	Association of Authorised and Accredited Persons
AO	authorised person
COV	Product Certification Bodies (Certification Bodies)
ČAS	Czech Standardisation Agency
ČOI	Czech Trade Inspection Authority
IO	inspection authorities
MMR	Ministry of Regional Development
MPO	Ministry of Industry and Trade
Ministry of Health	Ministry of Health of the Czech Republic
MZe	Ministry of Agriculture
MŽP	Ministry of the Environment of the Czech Republic
NO	Notified Body
NV	Government Regulation
OS	notified body
SÚJB	State Office for Nuclear Safety
SZV	Association of Construction Testing Laboratories
TNK	Technical Standardisation Committee
TZÚS	Technical and Testing Institute for Construction
ÚNMZ	Office for Technical Standardisation, Metrology and State Testing
ZL	testing laboratories for activities relating to the conformity assessment of construction products
NSZ	New Construction Act

17. Information sources

Websites:

https://ec.europa.eu/enterprise/sectors/construction/index_en.htm

https://eur-lex.europa.eu/homepage.html?locale=cs

https://www.unmz.cz

https://www.agentura-cas.cz

https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/

https://csnonlinefirmy.agentura-cas.cz/

https://www.iso.org/technical-committees.html

https://standards.cencenelec.eu/dyn/www/f?p=CEN:105:0:RESET::

https://www.eota.eu/

https://europa.eu/

https://europa.eu/pol/env/index_cs.htm

http://www.szv.cz

https://www.env.cz/

https://www.tzus.cz/

http://www.aaao.cz

https://nlfnorm.cz

https://www.mpo.cz/

https://zakonyprolidi.cz/

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

https://single-market-economy.ec.europa.eu/tris/

Annex 1 – Harmonised regulations and harmonised standards under NA

Sectors covered by Act No. 22/1997 Coll. (NA)	Abbreviation
Aerosol dispensers	AD
Refrigeration equipment	HRA
Noise emissions (NOI)	NOI
Exhaust emissions from spark-ignition engines in non-road mobile machinery	EGP
European rail system (high-speed and conventional) (placed on the market before 31 October 2020)	IRS
Toys	TOYS
Restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS
Personal protective equipment (placed on the market before 20 April 2019)	PPE-old
Transportable pressure equipment	TPED
Gas-fuelled appliances (placed on the market before 21 April 2018)	GAD
Construction products bearing the CE marking in accordance with CPR-2011	CPR-2011
Machinery	MD
Hot-water boilers firing liquid or gaseous fuels – efficiency (BED)	BED
Medical devices – active implantable devices (placed on the market before 26 May 2021)	AIMD
In vitro diagnostic medical devices (placed on the market before 26 May 2022)	IVDD
Medical devices (placed on the market before 26 May 2021)	MDD

Pyrotechnic articles	PA

Annex 2 – Harmonised regulations and harmonised standards under the NLF

Sectors covered by Act No. 90/2016 Coll. (NLF)	Abbreviation
Unmanned Systems	UAS
Low-voltage electrical equipment (NLF)	LVD
EU fertiliser products	FP
Simple pressure vessels (NLF)	SPVD
Cableways (NLF)	CAB
Marine equipment (NLF)	ME
Measuring instruments (NLF)	MID
Personal protective equipment (NLF)	PPE
Radio equipment (NLF)	RED
Recreational craft and personal watercraft (NLF)	RCD
Gas-fuelled appliances (NLF)	GAR
Construction products bearing the CE marking in accordance with CPR-2024	CPR-2024
Pressure equipment (NLF)	PED
Non-automatic weighing instruments (NLF)	NAWI
Explosives for civil use when placed on the market (NLF)	EXPL
Products in terms of their electromagnetic compatibility (NLF)	EMC
Lifts (NLF)	LIFTS
Equipment and protective systems intended for use in potentially explosive atmospheres (NLF)	ATEX
In vitro diagnostic medical devices (NLF – effective from 26 May 2022)	IVDR
Medical devices (NLF – effective from 26 May 2021)	MDR

Other sectors under the NLF	Abbreviation
Batteries (NLF)	BAT
Packaging and packaging waste (NLF) from 12 August 2026	PPWR
Harmonised rules for artificial intelligence (NLF)	AI

Annex 3 – Other regulations for which harmonised standards have been published

Other sectors	Abbreviation
New Horizontal Framework and Management Systems	NLF – EMAS
General safety (mandatory standards)	GPSD
Chemicals	REACH
Interoperability of European air traffic management	AT
Cosmetic products	CP
Packaging and packaging waste until 12 August 2026 in accordance with Directive 64/62/EEC	PPW
Sustainable use of pesticides	PAE
Postal services	CPS
Accessibility of public sector bodies' websites and mobile applications	AWMA
	IRS