



Placing of products on the Internal Market of the European Economic Area

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

Version 2024

This document is addressed primarily to manufacturers (established anywhere incl. in the Czech Republic) placing their products on the market of the European Economic Area (EEA).

It may be used also by importers of products to the EEA, distributors of products in countries of the EEA as well as authorised representatives established within the EEA, especially those established in the Czech Republic.

It can be useful also for staff members of authorized/notified bodies and recognised third-party organisations, fulfilment service providers, and end users of products.

It can be used also by associations of economic operators, training and educational organizations and institutions, national authorities, and other expert public.

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Foreword

The optimum way how to use this publication is to copy it to a PC with internet access and use the hypertext links to external information sources.

*All active links used in the publication (and many other) are listed in **Annex A**. In the relevant part of the text, the non-active link is represented by a number in square brackets – e.g. [A1.1]. The same number is used for the activated link in Annex A. The link can be opened by combination Ctrl+click or in any other way used by the concrete PC (creating a separate working file with Annex A will make the use of links prompter).*

*For easier understanding of the text, it is recommended first to pay attention to **Chapter 0** of this publication which contains basic **terms and abbreviations** (definitions) used in the text.*

Introduction

Supported by the Czech Office for Standards, Metrology and Testing – **ÚNMZ** – [A3.1] under the Standardisation Plan – Program for Development of Testing [A6.8] – the Association of accredited and authorised organisations **AAAO** [A3.2] issued in 2013, 2016, 2018, and 2020 publications for manufacturers (and other economic operators) from third countries concerning rules for placing of products on the internal market in the EU/EEA (hereinafter the **internal market**) [A1.11]. In 2015, 2017, and 2019, publications with the same subject matter and updated text were issued for economic operators in the Czech Republic.

Starting with “Version 2021”, the text has been consolidated for both economic operators in the Czech Republic (EU/EEA) and economic operators from third countries. In this form, the publication was issued in years 2021, 2022, and 2023.

The rules described in the following text apply generally to products posing a higher degree of danger to justified concern. They can be placed on the market provided (a.o.) their fulfilling of the essential requirements for products, activities of manufacturers etc. laid down in the legislation acts regulating entry of products on the market has been assessed.

This applies only to products, for which conditions for their entry on the internal market in the EEA [A1.11] are regulated by **EU harmonisation legislative acts of the “New Approach”** [A1.12]. These are currently being completed and replaced by **EU harmonisation legislative acts** (directives, regulations) of the “**New Legislative Framework**” [A1.13] for which these rules are also valid. Recently also legislative acts of the “**Goods Package: Reinforcing trust in the single market**” [A1.14] apply.

In the Czech Republic, these rules apply in principle also to other products placed on the market in accordance to the national Czech legislative acts not harmonised with the EU legislation.

In the Czech Republic, the rules described in the following text apply to products called in this publication “**specified products**”, see definition 026 in Chapter 0.

Information and recommendations in this publication are concerning specifically the placing of products on the market **in the Czech Republic**, which means also their placing on the internal market.

This publication describes only the **basic principles** which the manufacturer (established anywhere in the world) should not ignore when placing his products on the market in the EEA in accordance with the legislative acts of the EEA. Further details can be found in the information sources mentioned in Annex A of the publication (repeatedly, if appropriate).

These sources including information contained are subject to development and changes. Therefore, each user of the publication should always get and respect their **up-to-date version**. It is recommended to follow updates on the ÚNMZ website [A3.1] or in the ÚNMZ Information portal “Regulations and Standards” [A6.1] including its updates [A6.1.1] or in the ÚNMZ Information Portal “Placing of products on the market” [A6.1.5].

This publication therefore applies to various product sorts (or features common to more product sorts) described further as “sectors” [A5.1], [A5.6]. In different sectors, some rules are similar or even identical (rules being continuously consolidated), some differ for various reasons. This publication tries to grasp the main rules common to all sectors.

Note 1: Analogously to the Blue Guide 2022 [A6.1] this publication mentions but does not cover in detail the following areas:

- the Directive on General Product Safety [A2.1] and the EU rapid system for exchange of information “RAPEX” [A2.1.1] as well as relevant legislation;
- the EU legislation on motor vehicles, construction products, REACH [A7.9], and chemicals outside the list of “specified products” or above mentioned general aspects including the market surveillance;
- the EU legislation on food including chemical safety of materials in contact with food.

Note 2: Contrary to the Blue Guide 2022 [A6.1] this publication does not exceed the framework of basic information important mainly for manufacturers or other economic operators (see definition 029) and their activities before and after placing the products on market or putting into service (see definitions 028 and 028.1).

*Note 3: Only the **sector of construction products** is currently excluded from the publication. This specific area is described in Appendix 2. For links to information sources, see Annex A, Part 8.*

The main legislative act N305 (CPR) [A8.2] will be in short time – after redaction of the basic text of this publication (20 August 2024) – replaced by a new legislative act; please follow especially [A5.6.26], [A8.1], or [A3.1(CS)], [A5.2], [A6.12(CS)], [A6.13(CS)], [A6.15(CS)], [A8.11(CS)]. It is to be expected that meaning of some texts mentioned in this publication relating to N305 (CPR) [A8.2] will be changed. Such changes are not respected by this version of the publication.

0 Selected basic terms and abbreviations

01 ČR – Czech Republic, Member of the EU.

02 European Economic Area (EEA) [A1.1], or [A1.11] – consists of the EU Member States, Liechtenstein, Norway, and Iceland.

*Note 1: Countries outside this list are **third countries**.*

Note 2: Since 1 January 2021, the United Kingdom of Great Britain and Northern Ireland is regarded as “a third country”, see also [A1.17].

Note 3: Some rules applicable in the EEA apply also in relation to Switzerland and Turkey.

Note 4: In EU documents and quotations from them, “Union” is also used instead of “EU”.

03 Internal market [A1.11] – the market of the EU/EEA states to which a.o. free movement of products applies (see also 1.7 or 2.11 below); in the frame of the Custom Union Agreement the rules for free movement of products also enclose Turkey;

Note: If “market” is mentioned in further text, this means the “internal market”.

04 Regulated area – the public life area in which requirements and rules are laid down by special legislative acts;

Note 1: In this publication – for “specified products” (see definition 026) – concerns rather individual qualities than products, services etc. in the whole.

Note 2: The regulated area is much larger than the “specified products” area (see definition 026) and also much larger than the area in which a notified body (definition 020) is taking part in conformity assessment (definition 018).

Note 3: According to the Blue Guide 2022:

- in relation to accreditation: in the regulated area, accreditation may be required by legislative acts which is not the case in the non-regulated area;
- in relation to free movement of products in the EU: in the regulated area, EU harmonisation legislative acts may apply which is not the case in the non-regulated area.

05 Harmonised area – the part of the regulated area where the legislative acts containing rules and requirements are **harmonised within the EU** and replace individual national legislative acts with common regulation:

- either **directly applicable** (regulations), or
- **transposed** in all Member States (from EU directives into national legislation).

06 Non-harmonised area – the part of the regulated area where harmonisation within the EU has not been accomplished yet. In this area national requirements and procedures apply which for entry and movement of products on the internal market under the requirements laid down by legal legislative acts (e.g. in the Czech Republic Section 13b of Act 22 [A4.1]) can be regarded as **equivalent**; eventual problems are solved in accordance with **Regulation 515** [A2.6] – see definition 011.

07 EU harmonisation legislative acts:

- generally – legislative acts of the EU harmonising rules within the EU in areas where the Member States have agreed to harmonised texts;
- for this publication – all pieces of the EU legislation harmonising conditions for placing of products (specified – see definition 026) on the internal market.

08 New Approach [A1.12] – the set of EU activities and documents applied in the EU since ca 1985. It is based on laying down binding “essential requirements” in legislative acts with detailed specification in non-binding harmonised standards or other harmonised specifications.

Note: The process of creation of harmonised technical standards/specifications for the legislative acts is far from completed in the EU; for some acts there even do not exist [A7.6].

08.1 “The Blue Guides” or “BG ...” – documents published by the European Commission containing rules (more detailed than this publication) for placing most of “specified products” (definition 026) on the market in accordance with the **New Approach** [A1.12].

08.2 “The Blue Guide on the implementation of EU product rules 2022” (the Blue Guide 2022 or BG 2022) [A6.1] – containing rules for placing most of “specified products” (definition 026) on the market in accordance with the **New Legislative Framework** [A1.13].

09 Presumption of conformity – the basic principle of the New Approach [A1.12] – fulfilling of the relevant requirements of a harmonised specification (standard or other relevant document) is considered to be fulfilling of corresponding (essential) requirements of the legislative act.

Note 1: “Conformity with a standard” usually makes a reference to a situation where a standard is “fully applied”. This is for instance the case of voluntary certification against a standard.

Note 2: “Presumption of conformity” relates only to application of those provisions of the standard concerning the essential or other binding requirements for a product set by the regulations..The standard may also contain other parts not relating to essential requirements. And more, such standard may not cover all essential requirements.

010 New Legislative Framework (NLF) [A1.13] – the result of so called “revision of the New Approach [A1.12]” in the years 2005-2008 consisting of the following legislative acts:

- Regulation 515 [A2.6] – in force since 19 April 2020, replaces Regulation 764 [A2.2] (see definition 011.1);
- Regulation 765 [A2.3] (on 16 July 2021 amended by Regulation 1020 [A2.8]);
- Decision 768 [A2.4].

011 Regulation 515 – Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [A2.6];

*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States; in force since 19 April 2020).*

012 Regulation 765 – Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. [A2.3];

*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*

Amendments (incl. title) by Regulation 1020 [A2.8], Article 39 entered into force on 16 July 2021, the new title being “Regulation (EC) No 765/2008 of the European Parliament and of

the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93". See also definition 012.1.

012.1 Regulation 1020 – Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 [A2.8];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States; in force since 16 July 2021, some articles since 1 January 2021);*

013 Decision 768 – Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [A2.4];

014 Regulation 305 (CPR) – Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of **construction products** and repealing Council Directive 89/106/EEC [A8.2];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*

Amendments of Article 56 by Regulation 1020 [A2.8], Article 40 entered into force on 16 July 2021. See also definition 012.1 above.

015 Act 22 – in the Czech Republic only – Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended [A4.1]. It implements the New Approach [A1.12] principles into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **before implementation** of the New Legislative Framework [A1.13] (except for the Toys' safety Directive which is harmonised with its principles). Some government orders which do not transpose European harmonisation legislative acts have been issued for implementation of Act 22. In such cases no bodies are notified.

016 Act 90 – in the Czech Republic only – Act No. 90/2016 Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended [A4.2] – it implements principles of the New Legislative Framework [A1.13] (especially using Decision 768 [A2.4]) into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **in compliance with** the New Legislative Framework [A1.13].

017 Government orders – in the Czech Republic – in this form of Czech legislative act, the EU harmonisation legislative act (EU directive) is usually transposed into the Czech legislation. In this publication, only government orders issued for implementation of **Act 22** [A4.1], **Act 90** [A4.2] and **Act 206** [A4.3] are mentioned.

018 Conformity assessment

- according to Decision 768/Act 90 [A2.4/A4.2] – the process of demonstrating whether specified technical/essential requirements relating to a product, process, service, system, person or body have been fulfilled;
- according to the Blue Guide 2022 [A6.1] – the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled. A product is subjected to conformity assessment during both the design and the production phase;

- practical definition (for the Czech Republic and for this publication) – the set of activities by which fulfilling of relevant requirements of legislative acts valid in the Czech Republic (directly applicable, or harmonised with the EU, or national ones for the Czech Republic only) on performance of the product and activities of the manufacturer is ascertained, confirmed and documented for the specified products (see definition 026); fulfilling of the requirements is the condition for legal placing of the product on the market in the Czech Republic and thus on the internal market;

019 Conformity assessment body

- in the Czech Republic – according to Section 3 paragraph h) of Act 90 [A4.2] – a person or an organisational unit of the state performing conformity assessment activities including calibration, testing, certification and inspection;
- according to the Blue Guide 2022 [A6.1] – a body that performs one or several elements of conformity assessment, including one or several of the following activities: calibration, testing, certification and inspection.

020 Notified body – according to the Blue Guide 2022 [A6.1] – a conformity assessment body which has been officially designated and notified by their national authority to carry out the procedures for conformity assessment within the meaning of applicable Union harmonisation legislation when a third party is required.

It is the service supplied to manufacturers anywhere in the world. Notified bodies are notified by respective EU Member States (including the Czech Republic).

020.1 Notified bodies are listed in the database **NANDO** [A6.6]. In 2023, this database was incorporated into the Single Market Compliance Space system (**SMCS**) [A6.6.1] – see 020.2. The **NANDO** database enables search for subjects by countries, harmonisation regulations or numbers and contains details of the scope of activity, competence and contacts for each subject.

020.2 SMCS (Single Market Compliance Space) [A6.6.1] – the system, which combines the New Approach Notified and Designated Organisations (**NANDO**) and the Noise Emissions by Outdoor Equipment (**NOISE**) systems.

***Note 1:** The term “notified body” used in this publication covers **in the Czech Republic also subjects with different names** corresponding with the Czech legislative acts issued in the past: authorized body, recognized third-party organization.*

***Note 2:** The scope of notification is always specified for:*

- a product (product group);
- a legislative act or its part;
- and a module/assessment procedure with possible further specification.

***Note 3:** The scope of notification of different bodies is different, scopes of their activities overlap.*

***Note 4:** If the scope of notification of different notified bodies in one Member State does not cover all needs/obligations of manufacturers from the said Member State, services of notified bodies from other Member States have to be used.*

021 hEN – a harmonised European standard adopted by European standardisation organisation CEN, CENELEC or ETSI on the basis of a request made by the European Commission.

022 hČSN – in the Czech Republic only – a harmonised Czech standard created by taking over a harmonised European standard.

023 uČSN – in the Czech Republic only – a specified Czech standard.

024 ÚNMZ – in the Czech Republic only – Czech Office for Standards, Metrology and Testing (an organisational unit of the state) [A3.1].

025 ČAS – in the Czech Republic only – Czech Standardization Agency [A3.4] (a state contributory organization established by the ÚNMZ) [A3.1].

026 Specified product – only in the Czech Republic and for this publication – a product (sort of products) representing higher degree of endangering of public interest. Therefore, conformity of such products with legislative acts has to be ensured and assessed before their placing on the market. These products are (in the Czech Republic) **covered by:**

- a) **directly applicable** EU legislative acts concerning placing products on the market (the Czech legislation is adapted to these EU acts by means of Act 22 [A4.1] or Act 90 [A4.2], or other Czech legislative acts);
- b) Czech **Government Orders** issued for implementation of Act 22 [A4.1] or other laws. This concerns also products covered by Czech national government orders for selected products [A4.6] and selected construction products [A8.6] as well as products covered by the Atomic Act 263 [A4.5] and its implementing regulations [A4.5.1];
- c) Czech **Government Orders** issued for implementation of Act 90 [A4.2];
- d) **Act No 206/2015 Coll.** on pyrotechnics (hereinafter Act 206) [A4.3];

027 Making available on the market – any supply (including an offer or an agreement) of a product (meaning each individual product) for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]).

028 Placing on the market – the first making available (including an offer or an agreement) of a product (meaning each individual product) on the market (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]).

Note 1: The meaning may be made more precise in some sectors – for example for lifts Act 90 [A4.2] in Section 28, paragraph d) defines placing on the market as the supply of a lift for use on the market of the European Union...

Note 2: An individual product can be “placed on the market” only after its production has been finished and only once across the whole EU.

Note 3: A product for repeated renting is “placed on the market” only at the time the first renting takes place.

028.1 Putting into service – the moment of first use within the EU by the end user for the purposes for which it was intended (BG 2022 [A6.1]).

Note: In some EU harmonisation legislative acts this term is not relevant and in some acts its meaning may be modified.

029 Economic operators

- according to Decision 768 [A2.4] – the manufacturer, the importer, the distributor, and the authorised representative;
- according to Regulation 1020 [A2.8] – ditto plus the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant EU harmonisation legislation (see also definition 012.1 above).

Note: One legal subject may – for different products or even for the same product – be concurrently in the position of different economic operators.

030 Manufacturer – established anywhere in the world:

- according to Decision 768 [A2.4] – any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
- according to Act 90 [A4.2] – only in the Czech Republic – any person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark or uses it, if so stipulated by the Government in its Order, for his own use;
- according to Act 22 [A4.1] – only in the Czech Republic – any person who manufactures or just has designed a product, and where stipulated so by the Government in its Order, also a person who assembles, packs, processes or marks a product for which he is responsible under this Act and which he intends to place on the market under his name or trademark; where stipulated so by the Government for a product or for a group of products in its Order, as a manufacturer shall be deemed also a person who modifies a product already placed on the market in such a way that its compliance with the applicable technical requirements may be affected;
- since 16 July 2021 according to Regulation 1020 [A2.8] – any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark; ditto according to the Blue Guide 2022 [A6.1].

*Note: The term **manufacturer** covers in this publication in accordance with some EU harmonisation/Czech legislative acts also subjects responsible for the final product at products which are finalised (and thus placed on the market) at the place of use, often from components – products – from various manufacturers (e.g. lifts, some machinery, pressure equipment etc.). Namely, for lifts, the responsibility for a final product placed on the market (i.e. completed on the spot and put into use) lies with the **installer**, whereas the components for assembling the lift are supplied to him by their **manufacturers**.*

031 Authorised representative – established within the EU

- according to Decision 768 [A2.4] – any natural or legal person who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- since 16 July 2021 according to Regulation 1020 [A2.8] – any natural or legal person who has received a written mandate from a manufacturer to act on his behalf in relation to

specified tasks with regard to the manufacturer's obligations under the relevant EU harmonisation legislation.

Note 1: An authorized representative must not be mixed up with a commercial agent of the manufacturer.

Note 2: There is no obligation for a manufacturer established outside the EU to appoint an authorised representative.

032 Importer (established within the EU) – any natural or legal person who places on the market a product from a **third country** (outside the EU) – according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8].

033 Distributor (established anywhere) – any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the internal market – according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8].

034 Fulfilment service provider (since 16 July 2021 according to Regulation 1020 [A2.8]) – any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding any postal services or freight transport services.

035 End user (since 16 July 2021 according to Regulation 1020 [A2.8]) – any natural or legal person residing or established in the EU, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities.

036 CE marking – a marking by which the manufacturer on his responsibility indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing (according to Decision 768 [A2.4]);

037 Recall – any measure aimed at achieving the return of a product that has already been made available to the end user, to the person who has delivered the product to the end user (according to Decision 768 [A2.4]);

038 Withdrawal – any measure aimed at preventing a product in the supply chain from being made available on the market (according to the Decision 768 [A2.4]);

039 Non-compliance (since 16 July 2021 according to Regulation 1020 [A2.8]) – any failure to comply with any requirement under the EU harmonisation legislation.

040 Risk (since 16 July 2021 according to Regulation 1020 [A2.8]) – the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm.

041 Online interface (since 16 July 2021 according to Regulation 1020 [A2.8]) – any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products.

1 Basic rules for entry of a product on the market

1.1 A **product** can be **placed** on the market only if:

- a) it is **safe** – a product is safe if, under normal conditions – presumable, foreseeable – during its declared or normal usability does not present any risk or its use presents only minimum risk from the point of view of safety and health or protection of property and the environment which can be considered to be acceptable when using the product;
and if:
- b) it fulfils **essential requirements** of the legislative acts concerning health and safety or the environment provided the product is used in accordance with the manufacturer's instructions or within the “allowed/intended/supposed/foreseeable use”;
and if:
- c) it fulfils requirements of the legislative acts for **marking** of the product and for the **accompanying documentation** for use (especially instructions for use and safety information);
and if:
- d) its **conformity has been successfully assessed** by the procedure laid down by the relevant legislative act and the “**EU Declaration of Conformity**” (“EC Declaration of Conformity! according to the older legislation) or another document required by the relevant act has been issued.

1.2 The **manufacturer** of a product (irrespective of the country where he is established) is **responsible** for placing on the internal market only products meeting these requirements. The product (an identifiable piece, assembly, delivery and the like) must fulfil legal requirements in force **in the moment of its placing on the market**.

***Note 1:** The term **manufacturer** covers (in general and **everywhere** in this publication) also the subject responsible for a product assembled **on the place of use** (e.g. some machinery and pressure equipment).*

*Instead of the term **manufacturer**, the term **installer** is used only in legal acts concerning lifts where this term is properly defined. In the Czech legislation, the installer of a lift is defined in Section 28, subsection 2 of Act 90 [A4.2] as the person who is responsible for the design, manufacture, installation and placing of the lift on the market. Therefore, the installer of the lift is the person which takes over obligations attributed in other harmonisation legislative acts usually to the manufacturer.*

***Note 2:** The concept of **manufacturer** according to the EU harmonisation legislation based on the New Legislative Framework [A1.13] is different from the concept of **manufacturer** in Directive 85/374/EEC concerning liability of consumer products [A2.7].*

***Note 3:** Some EU harmonisation legislative acts contain also terms “**putting into service**” (e.g. lifts [A5.6.13]) or “**own use**” (e.g. machinery [A5.6.27]) to be used by the manufacturer himself) which are equivalent to “**placing on the market**”.*

1.3 The EU harmonisation legislation and the corresponding Member States' national legislative acts lay down requirements for placing of products on the market:

- **for manufacturers;** and

- for other **economic operators** – authorised representatives, importers, distributors, and according to Regulation 1020 [A2.8] (see definition 012.1 above) for fulfilment service providers.

1.4 The basic types of EU legislation from the point of view of their application in the Member States are:

- a) **directly applicable** EU acts – regulations (EU) of the European Parliament and of the Council or implementing regulations of the European Commission, or decisions of the European Parliament and of the Council. These acts are applied automatically and uniformly in all EU countries, without necessary transposition into the national legislation. They are binding in the whole scope for all EU countries. The countries issue only national legislative acts defining for example who fulfils obligations of authorities and persons laid down by such EU regulation.
- b) EU acts **intended for transposition** into the Member States' legislation – EU directives (currently the mostly used form, but in future directly applicable acts should be more frequent). Directives require that the Member States achieve the result but the way how they do it remains the Member State's choice. To achieve the goals set in the directive the Member States have to take appropriate measures for incorporation of the directive into the national legislation. National authorities are obliged to inform the European Commission about these measures;
- c) **delegated acts** – legally binding acts enabling the Commission to add or amend less substantial elements of the EU legislative acts, for example with the aim of defining the implementing measures. They are adopted by the Commission and if the European Parliament or the Council do not apply any protest, they enter into force;
- d) **implementing acts** – legally binding acts enabling the Commission (under supervision of committees consisting of Member States' representatives) set conditions for uniform application of EU legislative acts.

The European Commission publishes also **interpretative** documents (guidelines) supporting proper use of the legislative acts mentioned. Even though these guidelines are not legally binding, they are based on the consensus of all interested parties (legislators, representatives of economic operators, state and market surveillance authorities etc.) and contain guides, instructions and explanations for application of concrete articles in concrete situations. As these materials are widely respected, their knowledge and use is highly recommended.

1.5 According to Article 4 of Regulation 1020 [A2.8], a product may, in specified cases, be placed on the market only if there is an economic operator established in the EU who is responsible for the tasks set out in this article in respect of that product.

1.6 In the Czech Republic, basic legislative acts for the **harmonised area** of specified products are **Act 22** [A4.1] based on principles of the New Approach, and **Act 90** [A4.2] based on the principles of the New Legislative Framework, and **Act 206** [A4.3].

These principles cover sectors (areas) listed in **Annex A**, Part No. 5 of this publication, the current state can be followed in the **ÚNMZ Information Portal** "Regulations and Standards" [A6.2] in the following sections:

- a) product areas (sectors) to **Act 22** [A5.2];
- b) product areas (sectors) to **Act 90** [A5.3].

In addition to products from the above mentioned sectors (areas), in the Czech Republic products from the **non-harmonised area** (general [A5.6.34] and construction [A8.6]) are also covered by **Act 22**, see also 2.8.

1.7 Legal placing of a product on the market in any EU/EEA Member State (including the Czech Republic) means placing of the product on the internal market. If the product has been placed on the market in compliance with legislation of the state of placing on the market, such a product can be further distributed freely into other Member States without technical barriers on the Member States' borders.

Specific requirements such as requirements related to language of accompanying documentation for use of the product are laid down by relevant legislative acts of the Member State in which the products is distributed.

Problems with application of technical and administrative requirements of other Member State (which in the past were solved by Regulation 764 [A2.2]) have since its repeal been solved by Regulation 515 [A2.6].

1.8 A Czech manufacturer (similarly a third-country manufacturer) can, prior to placing his product on the market, fulfil the requirements of legislative acts by two ways:

- a) if he places his product on the market in the Czech Republic, he applies the relevant directly applicable EU harmonisation acts (EU regulations if they exist) and the Czech legislative acts transposing the EU harmonisation legislative acts;
- b) if he places his product on the market in another Member State, he applies the directly applicable EU harmonisation legislative acts and/or the legislative acts of this other Member State into which the EU harmonisation legislative acts are implemented.

1.9 The Czech Republic is an EU Member State. For manufacturers from the Czech Republic and for manufacturers and importers from third countries, it represents one of **possible entry states** for placing their products on the market in the Czech Republic and thus on the internal market.

1.10 The infrastructure of testing, inspection and certification bodies in the Czech Republic is both technically and legally competent. These bodies are able to provide all expert services with their mandatory assistance in the process of conformity assessment required by the legislative acts as well as voluntary services.

2 Technical requirements for products

2.1 The basic EU legislative act containing requirements for safety of consumer products is the new Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety etc. (see Item 10 in Appendix 1 and [A2.1.1]). Products covered by Directive 2001/95/EC [A2.1] which are in conformity with that Directive and which were placed on the market before 13 December 2024 may be made available on the market even after 13 December 2024 (see definition 027 in Chapter 0).

N988 a.o. enables the customers or other interested parties to inform the Commission about products which may represent a risk for health and safety of consumers, by means of the separate section of the **Safety Gate** Portal [A6.10]. For implementation of N988, the following three regulations have been issued:

- Commission Implementing Regulation (EU) 2024/1435 [A2.1.3] concerning the template for a recall notice;

- Commission Implementing Regulation (EU) 2024/1459 [A2.1.4] concerning the implementation of the interoperable interface of the Safety Gate Portal for providers of online marketplaces;
- Commission Implementing Regulation (EU) 2024/1740 [A2.1.5] concerning the modalities for consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers and for the transmission of such information to the national authorities concerned.

In the Czech Republic, Act No. 102/2001 Coll., on General Product Safety and on the amendment to certain Acts (Act on **General Product Safety**), as amended [A4.4] is in force. This Act relates to requirements for performance and placing on the internal market of products for which specific requirements of this type are not laid down by a specific EU harmonisation legislative act or a Member State's (e.g. Czech Republic's) legislative act.

Note 1:** If requirements for products performance are imposed by EU directives or directly applicable EU regulations, the **relevant part of the GPSD shall not apply.

*But one has to be **careful** – this should be seen from the point of view of **individual requirements (safety aspects)**, not of the complete product. There can be a situation when essential requirements from both a directive or an EU directly applicable regulation and GPSD requirements apply – the latter covering requirements/procedures not imposed by the directive or the EU directly applicable regulation.*

***Note 2:** The new regulation is the result of revision of Directive 2001/95/EC [A2.1].*

***Note 3:** For further details, see also the ÚNMZ Information Portal “Placing of products on the market” [A6.15], section: General safety.*

2.2 The EU **harmonisation legislative** acts with specific requirements for products and conditions for their placing on the internal market are predominantly the directives. For useful information, see the guides to the implementation of directives based on the New Approach and the Global Approach – the **Blue Guide 2022 – BG 2022** [A6.1].

2.3 The EU harmonisation legislative acts based on the New Approach [A1.12] use the principle of laying down only the **essential requirements** which are substantial for ensuring of safety of products and protection of health, property and the environment. The essential requirements represent the goal which has to be achieved (as far as the product safety is concerned), usually without specifying the way how to achieve it.

Detailed technical specifications of these requirements and technical ways how to fulfil them are included – provided they have been issued – in **harmonised technical specifications**, mainly in **harmonised European standards**.

2.4 In the formerly issued EU New Approach harmonisation legislative acts, conditions for placing of products on the market often vary in detail. As a result of practical use, the rules for the area of free movement of products on the internal market had to be made more precise and unified. Therefore the New Approach [A1.12] was revised and documents representing the “**New Legislative Framework**” (NLF) [A1.13] prepared. The NLF creates conditions for unification of substantial part of these rules. It consists of the following three documents – see also definitions in **Chapter 0:**

- Regulation (EU) 2019/515 of the European Parliament and of the Council (hereinafter **Regulation 515**) [A2.6];

- Regulation (EC) No 765/2008 of the European Parliament and of the Council (hereinafter **Regulation 765**) [A2.3] – in 2021 the title has been changed and some parts replaced by Regulation 1020 [A2.8];
- Decision No 768/2008/EC of the European Parliament and of the Council (hereinafter **Decision 768**) [A2.4].

2.5 Following principles of the New Legislative Framework, the process of adaptation of individual directives formerly issued in accordance with the New Approach is in progress. Some of the EC/EU directives have been or will be transformed into the form of directly applicable EU regulations.

The base for all these changes is Decision 768 [A2.4]. Hitherto different texts in some parts of the directives are being substituted with **uniform reference texts** of Decision 768. The recast does not concern essential requirements (with planned exceptions).

***Note 1:** Decision 768 [A2.4] as such is not intended for practical use. It represents only the binding guide for EU legislators. Nevertheless, it is very useful to familiarise oneself with its text, especially with the preambles explaining the principles.*

***Note 2:** Detailed and extensive preambles of harmonisation EU legislative acts contain useful explanations and justifications of binding parts of the texts. Therefore, it is most important to acquaint oneself with these parts in English version or in official (e.g. Czech) translations (see for example Annex A, part 5.6).*

***Note 3** If a product sector is covered by a directive in force, a parallel national regulation covering all relevant text of the directive is at the disposal of economic operators. If a directly applicable harmonisation regulation is in force, such regulation is used directly; in the Czech Republic, the regulation is implemented by a short national regulation laying down a.o. responsibilities of national authorities but no substantial details are mentioned.*

***Note 4:** Some principles of the New Legislative Framework [A1.13] set in Decision 768 [A2.4] begin being applied also in further EU harmonisation legislative acts which do not concern placing of safe products on the market (e.g. ecology, ecodesign, artificial intelligence, sustainability) – this is outside the scope of this publication.*

2.6 All EC/EU directives based on principles of the New Approach have been in the Czech Republic transposed into the government orders implementing **Act 22** [A4.1]. Some of them have been recast and newly issued following principles of the New Legislative Framework and are being transposed into new government orders implementing **Act 90** [A4.2].

2.7 For the monthly updated complex information about legislative acts and harmonised standards (with possibility of opening full texts), see the **ÚNMZ Information Portal** “Regulations and standards” [A6.2]:

- the product areas (sectors) under **Act 22** [A5.2];
- the product areas (sectors) under **Act 90** [A5.3].

***Note 3:** For further details of product sectors, see also the ÚNMZ Information Portal “Placing of products on the market” [A6.15].*

2.8 Apart from the government orders which represent transposition of EU harmonisation legislative acts into the Czech legislation, the Czech national legislative acts are in force in the Czech Republic:

- a) Act No. 263/2016 Coll., the **Atomic Act** [A4.5] and its implementing regulations (Decrees No. 358, 359, 360, 361, 362/2016 Coll.) [A4.5.1];
- b) Government Order No. 173/1997 Coll., that specifies selected products for the conformity assessment, as amended [A4.6];
- c) Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products, as amended [A8.6].

For placing on the internal market of these products as well as for their distribution, **Regulation 515** [A2.6] also applies.

2.9 Some NLF directives may be transposed into the Czech government orders implementing other laws than **Act 22** [A4.1] or **Act 90** [A4.2] (for example **Directive 2013/29/EU** of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles [A2.5]).

***Note:** The way of implementation of the EU harmonisation legislative acts into the national legislation differs in various Member States. When placing the specified products on the market in concrete Member State, one has to know perfectly this way and consistently follow it. For conditions in the Czech Republic, this publication may be useful.*

2.10 Many other product sectors (for example food products, cars, tractors, chemicals, medicinal products) **are not specified products** and are regulated in the EU by so called “**Old Approach**” directives or other legislative acts. These legislative acts apply to concrete product categories, are very detailed (and therefore very extensive), contain a.o. technical requirements, methods of their determination including conformity assessment, declaration and marking of conformity etc.

They are harmonised legislative acts in the EU; however they can be also non-harmonised legislative acts of the Member States.

Conditions for entry of such products on the internal market are derived from those legislative acts and often differ from the rules described in this publication for products called “**specified**” in the Czech Republic. Requirements and procedures from those legislative acts are **outside the scope of this publication**.

Products from those sectors, once legally placed on the market in an EU/EEA Member State enjoy the guarantee of **free movement** within the internal market on conditions laid down by those legislative acts and **Regulation 515** [A2.6].

Regulation 1020 [A2.8] introduces new provisions for placing of such products on the market common/unified with those for specified products.

2.11 For products not posing danger to justified concern **neither** harmonised “New Approach” documents **nor** “Old Approach” legislative acts **have been issued**. Nevertheless, even they have to fulfil the relevant **general safety** requirements (see 2.1). Even products from this **non-harmonised sphere** once legally placed on the market in an EU/EEA Member State enjoy the guarantee of **free movement** within the internal market.

***Note 1:** Possible problems with **free movement** of such products within the internal market were solved in **Regulation 515** [A2.6].*

*In doubt, the service of the **Product Contact Points** [A1.15] can be contacted. The contact points provide, free of charge, in each EU Member State a.o. information from the area of free movement of products in the non-harmonised sphere to entrepreneurs and authorities from other Member States. More precise information on Product Contact Points can be found in Regulation 515 [A2.6].*

*In the Czech Republic, the **Product Contact Point (ProCoP)** is currently established under the umbrella of Ministry of Industry and Trade [A1.16].*

Note 2: *For further details, see the ÚNMZ Information Portal “Placing of products on the market” [A6.15, section General safety].*

3 Obligations of and procedures recommended to economic operators

3.1 Common principles

3.1.1 Generally, each economic operator (manufacturer, authorised representative, importer, distributor, fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant EU harmonisation legislation – see definition 029 above) is obliged to ensure in the framework of his role in the supply chain that the basic rules for placing of his product on the market (and putting into use – e.g. lifts) and its distribution are fulfilled – see 1.1.

Especially the obligations of importers and distributors of specified products widely **exceed usual commercial practices**.

3.1.2 Obligations of economic operators are specified in the reference articles of **Decision 768** [A2.4]:

- obligations of manufacturers (R2), see also 3.2.1 below;
- obligations of authorised representations (R3), see also 3.2.2 below;
- obligations of importers (R4);
- obligations of distributors (R5).

3.1.3 If individual sectoral legislative acts differ from the general principles of Decision 768 [A2.4], then such specific provisions take precedence over the general principles. Direct application of Decision 768 [A2.4] without backup in the sectoral legislative act in force **is not allowed**.

3.1.4 Without prejudice to any obligations of economic operators laid down in the relevant EU legislative acts, Regulation 1020 [A2.8] summarizes and complements obligations of economic operators concerning placing of products on the market, especially in relation to efficient market surveillance. See also Article 4 of Regulation 1020 [A2.8].

3.2 Outline of obligations of economic operators (some possibly established also in the third countries)

3.2.1 Obligations of **manufacturers** apply to subjects established anywhere in the world. Topics:

- design and production in accordance with requirements of up-to-date legal legislative acts (even when the product or the legislative acts have been changed);

- drawing up of the technical documentation covering the product and its production;
- application of the required conformity assessment procedure in the pre-production and production stages;
- drawing up of the EC/EU declaration of conformity;
- affixing of the conformity marking (the CE marking or/and another marking if so required by legislation);
- keeping of the technical documentation (covering the product, its production and conformity assessment) and concerning the EC/EU declaration of conformity;
- identification of the product and the manufacturer on/at the product (a.o. to ensure traceability of the product);
- instructions and safety information for users in the relevant language;
- copy of the EC/EU declaration of conformity with each product (only if required by the relevant legislation) and/or its archiving for the specified period of time (a.o. for market surveillance authorities);
- tests of products prior to their placing on the market or putting into service (especially at mass or repeated production);

and after placing of the product on the market:

- corrective measures for non-conformed products, recall, withdrawal;
- evidence of complaints and of recalled products;
- informing of importers (of third-country products) and distributors;
- informing of market surveillance authorities;
- cooperation with market surveillance authorities;
- right to appoint an authorised representative (for activities specified in concrete legislative act).

3.2.2 Obligations of **authorised representatives** concern the subjects in the EU representing in the EU the manufacturer. Topics:

- establishing of the authorised representative within the EU (for example in the Czech Republic);
- performing of tasks specified in the written mandate from the manufacturer;
- keeping of the EC/EU declaration of conformity;
- keeping of the technical documentation;
- providing the surveillance authorities with information and documentation;
- cooperation with surveillance authorities in order to eliminate the risks posed by the product.

Depending on the conformity assessment procedure and the relevant EU legal act, the authorised representative may also be empowered to affix the CE marking (or other relevant markings) and draw up and sign the EC/EU declaration of conformity.

3.2.3 Obligations of **importers** concern subjects established within the EU.

3.2.4 Obligations of **distributors** concern subjects marketing specified products in the EU/EEA countries.

Note to 3.2.3 and 3.2.4: The economic operators have to know and require fulfilling of all obligations of all subjects in the distribution chain before them and have access to evidence of fulfilling of these obligations.

3.2.5 Since 16 July 2021, without prejudice to the above mentioned general obligations of economic operators and their detailed obligations laid down in the relevant EU harmonisation

legislative acts concerning placing of products on the market etc., economic operators have to fulfil a.o. obligations laid down in Chapter II of Regulation 1020 [A2.8].

3.2.6 Since 16 July 2021, without prejudice to the above mentioned general obligations of economic operators and their detailed obligations laid down in the relevant EU harmonisation legislative acts in relation to market surveillance authorities etc., economic operators a.o. have to cooperate with market surveillance authorities, realize the appropriate corrective actions imposed by market surveillance authorities to bring an instance of non-compliance to an end or to eliminate the risk and prevent damages, recover the costs of market surveillance authorities etc. as laid down in Chapter V of Regulation 1020 [A2.8].

3.3 Traceability

3.3 The New Legislative Framework [A1.13] and in the Czech Republic **Act 90** [A4.2] also lay down in detail the requirements on **traceability of products** which enables the market surveillance authorities to find the history of movements of the product. The traceability requirements are in particular:

- marking of the product;
- identification of economic operators in the distribution chain;
- keeping of technical documentation.

Economic operators are obliged a.o., for the specified period, to **identify** to market surveillance authorities all economic operators

- a) they bought the product from (their suppliers), and
- b) whom they supplied the product to (their customers).

3.4 Optimum procedures of the manufacturer

3.4.1 A manufacturer from the Czech Republic or from a third country can place his product on the internal market or put it into use in the Czech Republic or any EU/EEA Member State. This publication describes in the following text primarily situations when the entry state is the Czech Republic.

A manufacturer is obliged to supply the product **in conformity** with all requirements of the relevant EU harmonisation legislative acts and, if applicable, with requirements of relevant national legislative acts of EU Member States not covered by the harmonisation legislation.

3.4.2 To fulfil these requirements, the following basic steps have to be realised by the manufacturer, preferably in the described order:

- a) specification of the product, its purpose, for whom it is intended, its intended use etc. – this being the **base for successful completion** of all next steps;
- b) identification of all legislative acts applying to the product (Chapter 4);
- c) identification of requirements relating to the product performance (usually based on risk analysis) as well as to conformity assessment procedures laid down in the legislative acts (Chapter 5);
- d) identification and use of technical specifications (in the design phase of the product – in particular of harmonised European standards) related to the legislative acts and applicable to the product (Chapter 6);
- e) design of the product so that it meets requirements of the legislative acts (profiting from use of up-to-date technical specifications, in particular harmonised European standards if they exist);
- f) identification of the applicable conformity assessments procedures prior to placing of the

- product on the internal market (Chapter 7);
- g) choice of an appropriate (notified) conformity assessment body if its involvement in conformity assessment is laid down (Chapter 8);
 - h) realisation of the conformity assessment procedures (Chapter 9);
 - i) mandatory marking of the product (Chapter 10);
 - j) and supply of the accompanying documentation (Chapter 11);
 - k) production, possible conformity assessment procedures in the production stage and placing of the product on the internal market;
 - l) monitoring of information concerning use of the product including findings of market surveillance authorities and, if applicable, consequent measures related to design and following production of the (adapted) product.

3.4.3 It is useful to realise activities **a) to h)** during the **pre-production stages**; if realised later, additional costs may arise caused by changes of the product, the production process, sometimes even of the producing equipment, changes of production and other documentation etc.

3.4.4 Experience derived from results of activities **a) to g)** can to a large extent be **utilised repeatedly** even for other types/models of the same sort of similar products. If the manufacturer is adopting (and documenting) such procedures consistently during the first use, their subsequent use will proceed a lot more smoothly.

3.4.5 If the separate parts of products are manufactured in more countries, then it might be useful to realise activities **a) to h)** in the manufacturer's country. Tests, inspections etc. of a product specimen in the EU (for example in the Czech Republic) might also be taken into consideration.

3.4.6 Conformity of the product with essential requirements of the legislative acts has to be ensured for all products (pieces, batches etc.) during the whole period of their placing on the market. The measures ensuring fulfilment of this principle have to be performed in the production place (also in more places if substantial parts of the product are manufactured there). This applies similarly for services of notified bodies if their compulsory activities at conformity assessment cover also the production stage (see also Chapter 9.6).

3.4.7 Activities described under **h)** and **i)** have to be realised prior to placing of the product on the market.

3.4.8 The manufacturer, especially established outside the EU/EEA, may use the support of an "authorised representative" established in an EU Member State (i.e. also in the Czech Republic). The scope of activities of the authorised representative must be explicitly set out in writing, in conformity with the concrete legislative act(s) applying to the product – see also Decision 768, definition R3 [A2.4].

3.4.9 If anybody makes any changes of the product after its placing on the market (or during its distribution, definitely during use, etc.), he becomes the manufacturer. He is then obliged to realize all manufacturer's activities concerning possible consequences of the carried out changes for compliance with the legislative acts, results of conformity assessment, archived documentation of the product and production, accompanying documentation for the product's use, marking of the product etc. This has to comply with requirements of regulations applicable to the product.

4 Identification of legislative acts that apply to the product

4.1 There is no list for assigning a particular EU legislative act(s) to a particular product. This cannot be done even after transposition into the national legislation of a Member State, for example of the Czech Republic. Such an assignment can only be made (especially if it is for the first time) by analysing the system of existing legislative acts in force. Necessary conditions for it are among others identification of the product in question, intentions and aims of its development, future production and placing on the internal market, intended use etc. (see 3.4.2a above).

4.2 One or more pieces of legislation regulating its placing on the internal market may apply to one product simultaneously. The manufacturer has to fulfil and the product has to meet **all** relevant requirements **of all** applicable legislative acts.

4.3 For the first preview, whether the product in question is a specified product, the list of specified product sectors in Chapter 5 of **Annex A** of this publication can be used, with possibility of opening the **full texts** of legislative acts and harmonised standards. These sections are linked with the **ÚNMZ Information Portal “Regulations and Standards”** [A6.2]. For further information, see the ÚNMZ website **Sectors of specified products** [A5.1]. The relevant legislative acts can be identified by titles of the directives or regulations (on the EU website) or sectors and consequently of government orders on the ÚNMZ website.

4.4 The result of such survey is the **preliminary** list of the EU (or Czech) regulations (legislative acts) which **might be** applicable to the product.

4.5 The following necessary step is the detailed study of **preambles** of the identified sectoral legislation acts. The preambles usually explain which products the **act applies to**. And therefore, whether it applies to the product in question.

4.6 In general, exclusions of some products (types of products) from the scope of the legislative act are also laid down in the text. If this is the case and the product in question is covered by such exclusion, then the act **does not apply** to it.

4.7 This analysis has to be performed systematically **for all** identified sectoral legislative acts (according to 4.5 above) which might possibly apply to the product.

4.8 The result of this analysis is the **complete list of sectoral legislative acts** applying to the product in question.

***Note 1:** The scope of EU legislative acts laying down essential requirements for a product and rules for its placing on the internal market is in the Member States generally known in each professional sector. The relevant information can therefore be obtained also from the Member States' authorities (incl. the Czech Republic) or from professional groups in these countries.*

***Note 2:** Other legislative acts, even outside the New Approach area[A1.12], can apply to the product in question – for example the legislative acts concerning general safety (see Note to 2.1) [A2.1], consumer protection [A4.11], regulation REACH [A7.9] etc. The manufacturer and other economic operators in the supply chain have to fulfil relevant requirements of such legislative acts as well.*

4.9 The **responsibility** for correct assignment of all applicable legislative acts to the product **lies with the manufacturer**. In doubt, he may contact the **regulation's administrator** [A6.17] (in the Czech Republic) and ask for non-binding consultation.

Such consultation may be provided also by Czech notified bodies (see the list in [A3.1.1] or [A3.2.1] or [A6.6]/[A6.6.1] or [A6.6.3]/[A6.6.4]) or professional groups acting in the relevant product area/sector.

*Note: Any consultation with a notified body cannot be extended to expert cooperation how to fulfil the requirements – such activity of these subjects is regarded as **guidance** and as such **prohibited**.*

5 Identification of requirements of legislative acts

5.1 Each relevant sectoral legislative act specifies in its either body or annexes the “**essential requirements**” applying to all products covered by it. The requirements for the product in question have to be **identified**.

5.2 The essential requirements must be applied proportionately to risks connected with the product. Therefore, the manufacturers perform the risk analysis (obligatory in some sectors, useful in all) and specify all possible risks the product may cause and identify accordingly the essential requirements concerning the product. This analysis must be documented and included into the (archived) technical documentation especially when required by the relevant legislative act.

5.3 In addition, the manufacturer has to document how he solves the found risks in order to ensure the conformity of the product with applicable essential requirements and thus safety of the product (for example by fulfilling requirements of harmonised standards, if they exist).

5.4 If only a part of a harmonised standard is used or if such a standard does not cover all applicable essential requirements, then the way of solving of those relevant essential requirements not covered by that standard has to be documented (this applies similarly in the case when no harmonised standard exists for the product in question [A7.6]).

5.5 Only evidently irrelevant requirements (in respect of the product's purpose, intended use etc. – see 3.4.2a above) **may be excluded** from this analysis.

All other requirements have to be fulfilled. Their fulfilling has to be ensured by adequate measures applied to the product, its production, the accompanying documentation of the product, instructions for use especially for the user. This fact has to be consecutively **demonstrated and documented** by the following conformity assessment and documents resulting from it.

5.6 This analysis has to be repeated for **all legislative acts** applying to the product in question and identified according to the list in 4.9 above.

5.7 In the Czech Republic – for products to which some government orders implementing **Act 22** [A4.1] or a directly applicable EU regulation implemented by **Act 22** apply, **also** the relevant provisions of **Act 22** apply.

5.8 In the Czech Republic – for products to which some government orders implementing **Act 90** [A4.2] or a directly applicable EU regulation implemented by **Act 90** apply, also the relevant provisions of **Act 90** apply.

*Note to 5.7 and 5.8: For identification of requirements according to 5.1, Act 22 [A4.1] or Act 90 [A4.2] have to be taken into account as well and their relevant requirements **added (!)** to those from the Czech sectoral regulations.*

5.9 The result of this step is a (structured) **list of all requirements** for the product's performance as well as for manufacturer's activities identified **from all legislative acts** applying to the product in question.

Note: For identification of legislative acts applying to the product in question, the database of harmonised European standards can also be used – see [A6.4]

6 Identification of technical specifications related to legislative acts

6.1 The New Approach introduced the principle of “**presumption of conformity**”. If a requirement of a harmonised European/Czech standard (hEN/hČSN) is fulfilled, the corresponding “essential requirement” of the relevant legislative act **is considered** to be fulfilled as well.

*Note: but **nothing more!!!** Fulfilling of requirements of a standard (even if it is harmonised and clearly related to the product in question) does not mean automatically that **all** relevant essential requirements of the legislative act are fulfilled. The act may contain other essential requirements not dealt with by the standard (especially when new technologies, constructions etc. are involved).*

6.2 The harmonised European standards (hEN) give presumption of conformity only after **publishing of their references in the Official Journal of the European Union – OJEU** [A6.3]. Only new or withdrawn references of harmonised standards have been published in the OJEU (series L) by means of Commission implementing decisions related to the EU harmonisation legislative act in question.

The harmonisation of a European standard is always related to the relevant EU harmonisation legislative act. One European standard can be harmonised to one or more EU harmonisation legislative acts.

6.3 The harmonised Czech standards (hČSN) are transposed harmonised European standards. They are labelled ČSN EN, their number is identical with the relevant European standard – see [A3.4].

Note: A harmonised Czech standard is fully compatible with the harmonised European standard of the same title and number; references to both are equivalent.

6.4 The harmonised **Czech and European** standards can be effectively searched by using the monthly updated **database of all harmonised European standards** [A6.4]. Standards can be searched by parts of their title or by their numbers or by other criteria. For the given sector, the section “Harmonised standards grouped **by spheres**” can be used [A6.5].

Note: The same source of information [A6.5] covers also spheres other than placing of specified products on the market for which harmonised standards are also issued (chemical substances, air traffic, cosmetic products, packaging and packaging waste, inspection of pesticide application equipment, postal services, accessibility of the websites and mobile applications of public sector bodies).

6.5 To some EU harmonisation legislative acts and their corresponding Czech legislative acts, harmonised standards **have not been issued yet** [A7.6]. A manufacturer (in specified cases with participation of a notified subject) has to really ensure and demonstrate by documentation conformity with the essential requirements of the legislative act by using (if appropriate) for example:

- non-harmonised technical standards;
- other sectoral or manufacturer's own technical specifications;
- proven sectoral or manufacturer's own practices;
- known sectoral or manufacturer's own technical solutions;
- applicable scientific and technical knowledge;
- etc.

Note: See also 9.5.3 to 9.5.5 below.

In all such cases the conformity with all relevant essential requirements of the legislative acts identified in 4.9 above must be “directly” ensured and demonstrated (where the conformity is not demonstrated by use of harmonised standard/s).

Note: If more legislative acts apply to the product, then harmonised standards might exist (or might be used by the manufacturer) only in relation to some of them.

6.6 Although the use of harmonised standards for design, production and consequent conformity assessment of a product is not mandatory, it is very **advantageous** to the manufacturer. Of course, the manufacturer has (at least for the first time) to carry out an analysis as to whether the used harmonised standard covers all essential requirements of the applicable legislative act. Even those requirements that are not covered by the harmonised standard are to be **met** and their fulfilling **demonstrated**. Therefore, using of more harmonised standards or possibly other technical specifications within the conformity assessment of one product is by no means exceptional.

6.7 The cases when a harmonised standard exists but the manufacturer does not use it (especially in parts of guides concerning construction or other technical solutions) are uncommon. Even such solution is possible, because technical standards including harmonised ones are generally **non-binding**. For ensuring compliance with essential requirements of the legislative acts, documents and knowledge identifying the up-to-date state of the art and technical possibilities can be used (see 6.5).

Presumption of conformity with a harmonised standard cannot be used (logically). Nevertheless, the harmonised standard can be used for conformity assessment in parts identifying the required parameters, final requirements level, i.e. in general safety goals which are to be achieved during design and production.

6.8 If a manufacturer uses an existing harmonised European standard, he should always use the standard's latest issue reference to which is published in the OJEU [A6.3]. Such issue a.o.

legally reflects the state of the art (Decision of the Court of Justice of the European Union C-300/95).

It is therefore necessary for the manufacturer to monitor continuously updating of the harmonised standards/specifications he uses. He should react to their changes by changing the design or production and by updating the conformity assessment – for products newly placed on the market after the update of the formerly used harmonised standard/specification.

6.9 When a harmonised standard is concerned reference of which has been withdrawn from the OJEU due to the fact that some requirements of it do not ensure compliance with relevant essential requirements, available information on reasons of the withdrawal (especially in the relevant Commission implementing decision published in the OJEU [A6.3]) can be used for identifying the necessary level of technical requirements for the product.

Note: Harmonised standards are subject to revisions and are continuously replaced by new versions. If a reference to a new version of a European standard has not been published yet in the OJEU [A6.3] (see 6.2) as a harmonised European standard, only the withdrawn standard (if reference to it is still published in the OJEU) can be used for design of the product, its conformity assessment and CE marking until the reference to the new European standard is published in the OJEU as the harmonised European standard; for details, see also Statement of the ÚNMZ [A6.3.1]. During the transition period after the publication, both versions of the standard can be used for conformity assessment. The date on which the presumption of conformity of the superseded version of the standard ceases is usually indicated in the OJEU.

6.10 Distribution of texts of standards in the Czech Republic – for reading and for printing – is ensured by their publisher – since 2018 the Czech Standardization Agency [A3.4] – together with authorised dealers. For basic information – see the service **ČSN On-line** on the website of the Czech Standardisation Agency.

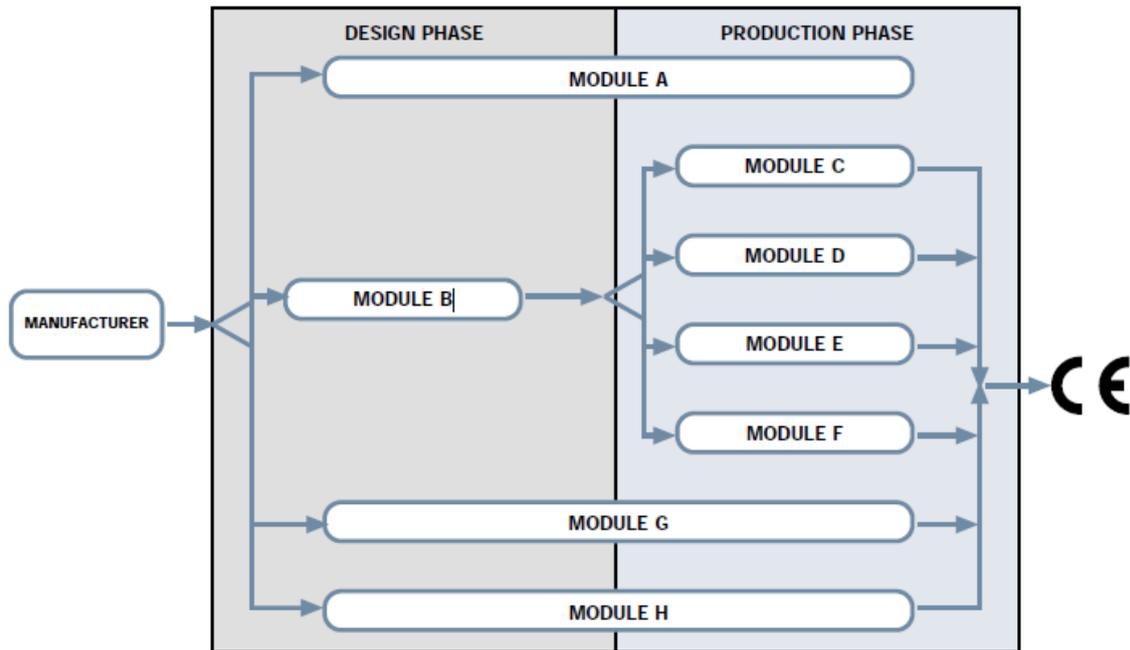
6.11 The **ÚNMZ Information Portal “Regulations and Standards”** [A6.2] contains monthly updated lists of harmonised European standards and corresponding Czech harmonised standards for individual sectors (including full texts of relevant legislative acts of the Czech Republic and the EU). Subscribers to the service **ČSN On-line** (see 6.10) may open **fulltext versions of harmonised European standards** directly from these updated lists.

Monthly updates of the portal can be followed in the **archive of updates** [A6.2.1].

7 Identification of conformity assessment procedures before placing of a product on the internal market or putting into use

7.1 Each legislative act contains in its either “body” or annexes the description of procedures (**modules**) for assessment of conformity of the product with essential requirements laid down in the act.

Annex II of R768 [A2.4] defines 8 basic modules A to H, and with their modifications together 16, named A1 to H1. Their systematic identification can be made in principle in the same way as identification of the essential requirements (see Chapter 5 above).



7.2 All modules and their variants are listed in Annex II of Decision 768 [A2.4]. This Annex II contains also the scheme of relations between the modules as well as their detailed description. The following topics are described there:

- module features;
- variants for various products and for various input conditions of the same type of products (for example using/non using of a harmonised standard, lists of products with specific mode);
- technical documentation on conformity assessment which the manufacturer/installer is obliged to draw up, keep and present to the notified body if he uses its services;
- involvement of a notified body in the process of conformity assessment, application for its services, results, information, communication;
- approval of a batch, production, quality system;
- controls of products, production, quality system, surveillance;
- declaration of conformity and conformity marking;
- keeping of documents and documentation;
- authorized representative;
- or other.

7.3 It is necessary to **repeat** the detailed analysis for each legislative act identified according to Chapter 4 of this publication as applying to the product in question.

The result is the (structured) **list of all conformity assessment procedures (modules)** and detailed inventory of partial activities which must be carried out during conformity assessment of the product.

The **crucial procedure** – independently of Decision 768 [A2.4], Act 22 [A4.1] and Act 90 [A4.2] – is the **procedure laid down in the concrete legislative act(s)** applying to the product, as identified according to 4.9 above. For the legislative acts, see product sectors [A5.6]. For further details concerning conformity assessment procedures, see the ÚNMZ Information Portal “**Placing of products on the market**” [A6.15].

Note: In a concrete sectoral legislative act, a conformity assessment procedure need not be indicated by the code from Decision 768 [A2.4], named as module nor references to text of Decision 768 are used.

7.4 Where more legislative acts apply to the product, the conformity assessment procedures may vary according to the individual acts. In such a case, the procedures have to be identified and then realised with respect for such variability.

And vice versa – if different legislative acts require the same procedure/module or the same partial activities within the modules (for example tests, inspections, certification etc.) then this procedure/module (including outputs) will be carried out only once but with differences in details if they are laid down in the individual acts.

7.5 The principal output from this analysis must be also the identification of **mandatory involvement of services of notified bodies** in the conformity assessment process. Scope of such mandatory involvement of a notified body may be:

- substantial to total;
- partial;
- none – basic variant of module A (or C).

7.6 Nevertheless, expert services (testing, inspection, certification etc.) of a subject serving for mandatory activities as a notified body can be used even for realisation of those parts of the assessment that are not mandatory but only as services carried out by an accredited (or non-accredited) subject. Results of such non-mandatory activities must not be presented as outputs of notified bodies.

7.7 Both types of services are provided on a **commercial basis**, with invoice for work carried out.

7.8 This analysis provides a.o. the **outline of mandatory conformity assessment procedures**.

The formalised result may be a list of required activities in the prescribed and logical order including competences, sources, outputs, documents etc. etc. (recommendable is for example a manufacturer's internal regulation).

Note: The conformity assessment procedures specify in the relevant module obligations of the manufacturer (see 3.2.1 above). This concerns especially cooperation with the notified body if its activity in the conformity assessment process is required. For information, see also the ÚNMZ Information Portal “Placing of products on the market” [A6.15].

8 Choosing the appropriate notified body

8.1 For realisation of mandatory involvement of a notified body (if laid down in the legislative act(s)), the manufacturer can choose any body notified for activities under the relevant **legislative act, product and module**. Generally there are more bodies notified under one legislative act. The scope of activities under one or more legislative acts can be different for each notified body.

The notified bodies are listed in the EU information system database **NANDO** (New Approach Notified and Designated Organisations) [A6.6] enabling searching of bodies by countries, directives and other criteria.

In the Czech Republic, the following sources can be used:

- the list of Czech notified bodies in **NANDO** (with their scope of activity) [A6.6.1];
- the list of notified bodies in the Czech Republic on **ÚNMZ** websites [A3.1.1].
- the list of **AAAO** members [A3.2.1] and their websites (but not all Czech notified bodies are members of AAAO);

8.2 The notification in the Czech Republic is realised by **ÚNMZ** [A3.1], the Czech notified bodies (see definition 020) being published in the electronic EU database **NANDO** [A6.6.1].

ÚNMZ – Czech Office for Standards, Metrology and Testing [A3.1] – is a state administration body acting a.o. in the area of activities described in this publication. Within its responsibility in the Czech Republic in relation to conformity assessment bodies, **ÚNMZ** among others:

- assesses competence of applicants for authorization and notification (according to Act 22 [A4.1]), Act 90 [A4.2], and Act 206 [A4.3];
- notifies the assessed bodies to the European Commission and other EU Member States;
- publishes authorizations and notifications in the Journal of the Office [A6.7];
- creates conditions for their uniform procedures;
- monitors their activities;
- solves some offences, administers sanctions etc. at breach of Act 22 [A4.1], Act 90 [A4.2];
- cooperates internationally in these areas.

For details, see **Act 22** [A4.1] and **Act 90** [A4.2].

For an outline of all **ÚNMZ** activities, see [A3.1].

8.3 Applicants seeking authorization and notification demonstrate their expert competence for the conformity assessment activities preferably by means of accreditation in compliance with **Regulation 765** [A2.3], together with Regulation 1020 [A2.8], if applicable. Accreditation in the Czech Republic is performed in accordance with Regulation 765 by the only Czech accreditation body – **Czech Accreditation Institute (CAI)** [A3.3]. Rules for accreditation as well as the scope of accreditation of individual organizations can be seen on the CAI website [A3.3.1].

Note: Regulation 765 [A2.3] was amended by Regulation 1020 [A2.8]. The amendment concerns both the title and some provisions – see Article 39 of Regulation 1020.

8.4 The notified bodies can provide their service to manufacturers established both in and outside the EU. Documents on conformity assessment identified as outputs of the work carried out by bodies within the framework of their notification (incl. those established in the Czech Republic) are **valid/usable** within the whole EU/EEA (but not outside this area).

8.5 The expert competence and offer of services of notified bodies, members of the AAAO [A3.2.1] and others, is in general broader than their activity in the position of a notified body. It is demonstrated among others by means of accreditation but in particular for activities **outside the framework of notification** also in other ways – long tradition, customer references, membership in international groups of similar subjects, leading role in standardisation activities etc. etc.

This is the reason for use of the same subject even for non-mandatory tests, inspections and certifications. The manufacturer may in this manner, for example, demonstrate the conformity with requirements of a legislative act in the cases where involvement of a notified body is not mandatory. Moreover, he may demonstrate to his customers the performance of his products, credibility of his procedures etc. even beyond the scope of obligations derived from the legislative acts.

Such activities comprise, for example, certification of management systems according to the ISO 9000 and 14000 series of standards etc. – see the **list of AAAO members** [A3.2.1] and detailed information (names of these subjects also in English and Russian) on their respective websites.

9 Realisation of conformity assessment procedures

9.1 Responsibility

It is always the **manufacturer, irrespective of the country where is established**, who is **responsible** for correct and complete realisation of conformity assessment procedures in compliance with the applicable legislative acts. The manufacturer is responsible whether the involvement of conformity assessment bodies is required by the legislative acts or not.

9.2 Procedures

The conformity assessment procedures and their variants for different situations relating to the same product are described in detail in the individual legislative acts. Legislative acts reflecting **Decision 768** [A2.4] use various types of modules (see 7.1 above).

9.3 Risk analysis

9.3.1 Some modules prescribe the **risk analysis** with regard to the product safety. It is most useful also when using other modules.

9.3.2 Irrespective of sector and product differences, the first step of the analysis performed for the product in question is **identification of all risks** with possibility of substantial **damages**. By means of a “dialogue” between the essential requirements of the applicable legislative acts plus consequential specifications/harmonised standards and design/construction/performances of the product, the relevant requirements (ca = risks) are identified including those not solved by these documents (see also Chapter 5).

9.3.3 The next step is the evaluation of importance of each risk from the point of view of damages that might happen at a loss incident. This importance depends on

- a) probability of realisation of the risk to loss;
- b) supposed amount of loss;
- c) and – by more sophisticated analysis – vice versa on the probability and possible scope of averting of realisation of the risk to loss.

9.3.4 According to this importance, the differentiated measures are to be accepted for elimination of the risk. It is (formally/methodically) outside the analysis but this is the **goal of the whole activity**, so separation or termination would be contradictory. For the product itself it means:

- a) to eliminate sources of **unacceptable risk** or by means of concrete measures prevent possible realisation of the risk to loss, independently of specified/approved/expected use of the product;
- b) to solve **residual risks** by means of safety marks (pictograms) and inscriptions on the product, safety instructions in the accompanying documentation for use of the product, laying down and fulfilling requirements for qualification of personnel, training of personnel etc.;
- c) not to solve (after careful evaluation) **negligible risks** (or only mention them in the accompanying documentation to the product for the user).

9.3.5 All measures must be subjected to validation (in real conditions) with checking of their efficiency and possibly (according to the result of the validation) repeated or modified. The final goal is to prevent damages in real life of the product (during its intended, specified or usual time of use).

9.3.6 It is also useful to start the analysis as soon as possible (in the pre-production stages) and subsequently make it more precise.

9.3.7 The higher level of the analysis is its “extension” to the period of expected long-term **use** of the product. The result is then for example the program of planned preventive measures during use – for example planned safety-related monitoring/checks/controls/revisions, planned maintenance and repairs carried out according to either plan or monitored state, with renovation/exchange of risky parts of the products with shorter service life than the whole product etc.

***Note 1:** The safety by using products may be covered by special legislative acts, both harmonised in the EU and national in the Member States; the border between them and those mentioned in this publication is usually not clearly determined. For examples, see [A2.11] and [A2.12].*

***Note 2:** For some products/sectors, the risk analysis is described in technical standards/specifications; various procedures are used with special terminology etc. (e.g. ČSN EN ISO 12 100). The above mentioned principles are the same and applicable also in other situations and are generally described (also for other areas of use) for example in ČSN ISO 31 000 (principles) and ČSN EN 31 010 (techniques). Attention should be paid also to ČSN EN 60 812 (FMEA), ČSN EN 61 025 (FTA), ČSN EN 62 198, and ČSN ISO 21 500 (risks of projects).*

***Note 3:** Practical experience has shown that the measures resulting from the risk analysis may/must concern not only the product itself. Then, a useful guidance for a manufacturer can be a detailed risk analysis in relation to measures in the market surveillance area where cooperation of economic operators is required as laid down in Regulation 1020 ([A2.8] and definition 012.1).*

According to Regulation 1020 ([A2.8] and definition 012.1), products are (in relation to risks) specified as follows:

- a) “**product presenting a risk**” (... having the potential to affect adversely health and safety ... to a degree which goes beyond that considered reasonable and acceptable ...);
- b) “**product presenting a serious risk**” (... considered to require rapid intervention by the market surveillance authorities ...);

Although a “product” is mentioned here, the examination has apparently cover individual qualities/risks.

Note 4: According to Regulation 1020 [A2.8], the corrective action to be taken by the economic operator may include, among others:

- a) bringing the product into compliance with regulations ...;
- b) preventing the product from being made available on the market;
- c) withdrawing or recalling the product immediately and alerting the public ...;
- d) destroying the product or otherwise rendering it inoperable;
- e) affixing warnings to the product ...;
- f) setting prior conditions for making the product available on the market;
- g) alerting the end users at risk ...

Market surveillance authorities ensure that products are withdrawn, where there is no other effective means available, or that their being made available on the market is prohibited.

9.4 Conformity assessment without participation of a notified body

9.4.1 A substantial part of praxis in conformity assessment is covered by “**module A**”, which **does not prescribe involvement** of a notified body in the conformity assessment process. Similarly for the basic variant of module C.

The technical activities (tests, inspections etc.) may be then:

- either carried out by the manufacturer himself, provided he is technically, personally etc. equipped for doing so;
- or carried out with utilisation of external services of competent organisations. These should be first of all the organisations accredited [A3.3.1] according to globally united rules, published on the website of **CAI** [A3.3].

9.4.2 It is the manufacturer’s choice and responsibility whom he will use. Accreditation of the organisation used at conformity assessment according to module A (or C) is not mandatory but poses an indisputable argument of demonstration of competence and impartiality.

Note: This can, to a certain degree, be applied even if the organisation’s accreditation does not cover its concrete used services. This is because the accreditation requirements apply not only to a concrete “accredited activity” but to the whole organisation, thus influencing (positively) credibility of its “non-accredited activities” as well.

9.4.3 The organisation with a notified body status can also provide non-mandatory services but not as a notified body – only as an accredited subject (within the scope of its accreditation certificate [A3.3.1]) or, in extreme case, as a competent but not accredited subject (see 8.5). In such a case, increased attention should be paid to impartiality risks.

9.4.4 Any activity of an organisation with the notified body status **must not** have the character of guidance with **instructions** how to fulfil the relevant requirements on product performance or how to eliminate discrepancies in fulfilling these requirements.

9.5 Conformity assessment with participation of a notified body

9.5.1 Most modules lay down **mandatory involvement** of a notified body in the conformity assessment process. These modules/procedures require that the manufacturer asking for the notified body’s service deliver to the notified body, with his application, also the technical

documentation (its scope according to the relevant module) including a.o. the test/inspection protocols already acquired by the manufacturer.

The tests or inspections at this stage, i.e. prior to manufacturer's application for the notified body's conformity assessment service, have to be handled in principle in the same way as described in 9.4 above.

9.5.2 The notified body has to carry out (or make carry out) these tests and activities which are prescribed by the relevant module (and possibly specified in the specifications, especially in the harmonised European standards or harmonised Czech standards). If the notified body plans to subcontract (with mandatory agreement of the client) tests or inspections to another organisation, this organisation must as a **subcontractor** fulfil practically the same requirements on competence, impartiality etc. as the subcontracting notified body. The full responsibility to the manufacturer for the work of the subcontractor lies with the subcontracting notified body.

Note: A notified body can only subcontract a task for which it has the competence itself (Blue Guide 2022 [A6.1]).

9.5.3 Where the **harmonised standards do not exist** or the manufacturer **has not used** them or has used them only **partly** the notified body applies specific procedures. This situation requires very close cooperation with the manufacturer.

The notified body examines the solution and technical specifications – checks whether all relevant essential requirements have been fulfilled and stated in the technical documentation file and whether the solutions and technical specification used meet the essential requirements. Doing it, the notified body takes the current state of the art into account.

9.5.4 In general – the technical solution for fulfilling the essential requirements of the legislative act, if a harmonised standard **is not used**:

- a) may be laid down in a technical standard (non-harmonised) or in other technical specifications;
- b) or drawn up by the manufacturer (or association of manufacturers of the same product, qualified subjects acting in the sector etc.) in compliance with the general technical and scientific knowledge stated in technical and scientific literature;
- c) or drawn up by the manufacturer (or association of manufacturers of the same product, qualified subjects acting in the sector etc.) from experience of development, production and use of similar products, of safety proved in praxis etc.

Such flexibility enables manufacturers to choose own way how to fulfil the requirements. It enables for example to adjust materials and design of the product to technical state of the art. In these cases, the manufacturer cannot use the presumption of conformity but has to prove compliance with the legislative act on his own. It means that he demonstrates in detail in the technical documentation to the product how the technical specifications he uses ensure the conformity with essential requirements. For more information, see Article 4.1.3 in the Blue Guide 2022 [A6.1].

9.6 Conformity assessment in mass production

9.6.1 The manufacture has the general obligation to ensure that **every piece** (batch, package) of the product he is placing on the market meets all relevant requirements of legislative acts.

The framework for conformity assessment of products from repeated/mass production is based on the modular structure (see 7.1):

- either on “**EU-Type examination**” in the pre-production stage (module B) together with one of other modules ensuring compliance with this type in the production stage (module C and variants, modules D, E and F); or
- on operating of a “**quality assurance system**” in the pre-production and production stages (modules D1, E1, F1, G, H and H1); or
- on “**internal production control**” (module A and variants).

Note 1: Some principles are combined in different module variants.

Note 2: Where more modules apply for a product, different notified bodies may be involved in conformity assessment according to the modules (if their involvement is required).

9.6.2 First of all, the product itself (its specimen as the representative of the product type/model) is assessed. Then assessment of the production (possibly also pre-production stages) follows according to various modules and their modifications even with participation of a notified body. The extent can be from assessment/approval of the production process (in the production place) to taking samples of products from mass production, often with the following supervision, either planned or random.

9.6.3 In the third case, the manufacturer ensures the compliance of the manufactured products with the technical documentation by means of internal production control.

9.6.4 The provisions from the **concrete legislative acts** applying to the product according to Chapters 4 and 5 are binding.

9.7 Archiving of conformity assessment results

9.7.1 Individual legislative acts lay down which documents on conformity assessment the manufacturer has to draw up or collect. The documents can be systematically identified similarly to Chapter 5 above.

9.7.2 Important is the obligation to **archive** these documents even after placing on the market of the last item of the relevant product. Act 22 [A4.1], Section 13, subsection 7 lays down the general period of 10 years which may be laid down differently by an EU harmonisation legislative act and subsequently by concrete government orders. Act 90 [A4.2], Section 6, subsection 2 does not lay down any general period of time leaving it to the government orders. In general – see the sectoral legislative acts [A5.6].

9.7.3 Traceability of documentation is also very important. For every **piece/batch/packing** of the product, the concrete relevant version of documents (incl. the declaration of conformity – see later) must be enabled to be searched out, if possible within the required period.

9.8 Declaration of conformity

9.8.1 After accomplishing all required conformity assessment procedures with positive results, the **manufacturer draws up** the “**EU declaration of conformity**” (or “EC declaration of conformity” according to the still valid old legislative acts). The declaration a.o. identifies the

issuing subject (manufacturer or authorised representative), the product (piece, batch etc.) concerned, regulations with which the conformity is declared etc.

The concrete form and content of the declaration are laid down by the provisions with which the conformity is assessed and declared.

9.8.2 Where a notified body is involved in the conformity assessment procedures, the certificates and other documents issued by it serve (together with other documents) the manufacturer as materials for drawing up the declaration.

However, they **cannot substitute** this declaration!

9.8.3 The product's "**admission ticket**" to the market (and/or to use) from the point of view of requirements laid down by the EU harmonisation legislation is the **EU/EC declaration of conformity**, not a certificate or any other document issued by a notified body, even if it looks "officially"!!

9.8.4 According to the New Legislative Framework, the manufacturer draws up only **one single and common EU declaration of conformity**. The single declaration of conformity can be made up of a dossier containing all relevant individual declarations of conformity provided the concrete legislative act enables it.

Where the final usable product is assembled on the spot from components of various origins, the relevant legislative acts lay down how the declaration of conformity should be drawn (including responsibility for it), its form, contents etc,

9.8.5 Some legislative acts require **each piece/batch/packing of the product** to be accompanied by the "EU/EC declaration of conformity" or specify **other ways** of its keeping or using.

9.8.6 The rules for conformity assessment and the declaration of conformity do not affect the possibility for the manufacturer to order, on commercial base, from an organisation which has also status of the notified body even other non-NB supporting documents (for example voluntary test protocols, inspection reports/protocols, certificates etc.). The organisation has to perform this as an accredited subject outside the scope of the notified body's activities.

9.8.7 According to Regulation 515 [A2.6], it is now possible to draw up a declaration of lawful marketing of goods for the purposes of mutual recognition ("**mutual recognition declaration**"). It concerns situations when a product is placed on the market according to the **EU-non-harmonised national regulations**. This declaration demonstrates to the competent authorities of any Member State of destination that the product is lawfully placed on the market in the Member State of manufacturer or importer.

This declaration has to comply with provisions of Article 4 of Regulation 515 [A2.6], follow the structure set out in Part I and Part II of the Annex of Regulation 515 and contain all the information specified therein. If an EU legislative act requiring a declaration of conformity applies to the product, the mutual recognition declaration may be attached to the declaration of conformity.

The mutual recognition declaration shall be drawn up in one of the official languages of the EU, and, if applicable, with translation into a language required by the Member State of destination.

Note: For further details, see also the ÚNMZ Information Portal "Placing of products on the market" [A6.15].

10 Mandatory marking of the product

10.1 The **CE marking** is the common visual information on the product declaring that the requirements of EU harmonisation legislative acts are fulfilled. It means that compliance of the product with requirements of the relevant EU harmonisation legislative acts laying down or enabling the CE marking has been **verified and confirmed** prior to placing of the product on the market and therefore the product can be placed on the market. The CE marking is obligatory if laid down by relevant EU harmonisation legislative acts applying to the product in question. It is affixed to products placed on the market in the EEA (and Turkey) regardless of production place.

10.2 The CE marking, if affixed rightly, declares that the manufacturer/installer respected all applicable legislative acts and made everything what was his obligation (and maybe even within his power at current state of the art) for the safety of the product.

Relevant EU procedures enable operative reaction to changing situation by adaptation of harmonisation legislative acts, harmonised specifications as well as activities of economic operators, notified bodies and surveillance authorities.

10.3 General principles for the **CE marking** (see the picture at the beginning of this publication) are laid down in Annex II of **Regulation 765** [A2.3] (see also definition 012 in Chapter 0), further details are specified in the concrete legislative acts applying to the product. Following the New Legislative Framework [A1.13], conditions for affixing the CE marking are also described in Decision 768 [A2.4] and in relevant legislative acts as well as in the corresponding harmonised standards/specifications (details may differ in various product sectors).

10.4 For products assembled at the manufacturer's site, the CE marking is attached, prior to placing of the product on the market, by the manufacturer himself or by his authorized representative. For products assembled on the site of their use, the CE marking is attached, prior to putting of the product into use, by the installer of the product, after decision of the notified body concerned.

10.5 The CE marking is to be affixed to the product itself, attached label or packaging. Electronic CE marking (depending on supply of electricity, unstable by failures etc.) **is not** allowed.

10.6 Some pieces of legislation require the CE marking to be accompanied by the identification number of the notified body involved in the conformity assessment.

10.7 Apart from the CE marking, other marks and markings (both mandatory connected with CE and voluntary) can be affixed to the product.

Some pieces of legislation provide for **special conformity marking** (instead of CE), for example:

- a) the wheel mark (directive on marine equipment [A5.6.3]);
- b) the "Pi" symbol (π - directive on transportable pressure equipment [A5.6.24]);
- c) the "3" symbol (inverted epsilon – ε – directive on aerosol dispensers [A5.6.16]).

10.8 According to some directives, the CE marking can be followed by other compulsory markings, for example:

- a) the pictogram with indication of the guaranteed sound power ( – directive on the noise emission in the environment by equipment for use outdoors [A5.6.18]);
- b) the supplementary metrology marking consisting of a rectangle (of the same height as the CE marking) with capital “M” and last two digits of the year in which the marking was affixed (directive on measuring instruments and directive on non-automatic weighing instruments [A5.6.4] and [A5.6.10]);
- c) the specific marking of explosion protection ( – directive on equipment and protective systems intended for use in potentially explosive atmospheres [A5.6.14]).

10.9 Also other markings not connected with CE may be placed on the specified products. However it is forbidden to affix marks, markings or inscriptions which could confuse third parties as to the meaning or form of the CE marking. Any other marking may be affixed to the product provided its affixing does not impair the visibility, legibility and meaning of the CE marking.

10.10 Further details concerning marking of the concrete product are laid down in the relevant sectoral legislative acts. These were, logically, used also for the conformity assessment of the product. Unfortunately, it must be said that in this part individual legislative acts (even the harmonisation ones) still differ.

10.11 Obligation or possibility of use of the CE marking is also laid down in other pieces of EU legislation (and in transposed legislation of the Member States incl. the Czech Republic), though they cannot be regarded legislative acts from the area of placing of specified products on the market. Provisions contained in these acts may differ from the rules described in this publication (for example the **ecodesign** of products) [A7.8].

11 Accompanying documentation

11.1 This documentation accompanies the product from its production (even from its pre-production stage) till its liquidation after the end of its life. The author of the accompanying documentation is mainly the manufacturer.

Requirements for the accompanying documentation are specified in the legislative acts and harmonised technical specifications. The documentation reflects also the results of design/development of the product, tests and verification of prototypes/first samples, preparation of production as well as results of conformity assessment of the product. So it is original from the point of view of the product as well as of the manufacturer.

11.2 The **first big group** of possible documents is predominantly an internal concern of the manufacturer and is connected with construction of the product which is important at its placing on the market and putting into operation. The aim to preserve operating and safety performance invested into the product during its development and production, its further “technical life” etc.

11.3 Examples of topics in the first group – instructions for:

- a) storage after the production;
- b) adjustment (before transport);
- c) packing;
- d) transport;

- e) storage at distributors;
- f) assembling and putting into operation, testing in operation etc. (if it is in responsibility of the manufacturer/supplier as part of delivery);
- g) pre-sell service (in responsibility of the manufacturer/supplier);
- h) guarantee service, post-guarantee standard service (in responsibility of the manufacturer/supplier, his contractors etc.);
- i) expected replacements of worn-out parts (in responsibility of the manufacturer/supplier, his contractors etc.);
- j) diagnostics including HW and SW (in responsibility of the manufacturer/supplier, his contractors etc.);
- k) system and distribution of spare parts (in responsibility of the manufacturer/supplier, his contractors etc.);
- l) expected troubleshooting (in responsibility of the manufacturer/supplier, his contractors etc.);
- m)etc.

The list need not be exhaustible and is not limited, contains also non-actual items for some products.

11.4 The **second** possible or rather **necessary** group of documents is intended for end users of products (both legal and private persons). It is connected primarily with use of products and activities of users. It is derived from requirements of legislative acts and connected technical specifications, with substantial and reasonable sectoral and product differences. It reflects results of the risk analysis, conformity assessment etc.

The aim is to ensure safety of users in the sense of life and health protection as well as protection of the environment and property. An important factor for manufacturers and other economic operators is also protection against damages caused by using the product (especially improperly) and protection against sanctions resulting from non-fulfilling the requirements of legislative acts (i.e. incorrect placing of the products on the market, their lawless distribution, improper accompanying documentation, losses caused by faulty products etc.).

These documents in general reflect information and guidance for efficient use of the product in compliance with the purpose for which the manufacturer the product developed, produced and placed on the market.

11.5 **“Instruction for use”** is a typical document from the second group. Its name may vary, it may consist of more documents etc. but this document must contain everything which is for the product required, necessary and sufficient. Complementing of the text with pictures, schemes etc. makes it more effective and attractive.

***Note 1:** Generally – in many situations it is necessary to distinguish between the “owner” of the product and its actual “user/operator”. The owner has towards the user/operator (and vice versa) of the concrete product many obligations and responsibilities, often resulting from conditions set by the owner.*

***Note 2:** For example, for technical equipment the “Instructions for use” is the most important document which informs the owner about WHO, WHEN and HOW may possibly change its construction without loss of guarantee rights and liability of the manufacturer/installer for possible damages caused by the defect product to the owner/user/third party.*

11.6 Examples of topics in the second group:

- a) general specification of the product, its purpose, to whom it is intended, way of use etc.

- (see also 3.4.2a);
- b) method of identification of type, variant, item, production date of the product (a.o. for communication with manufacturer, distributor, service, supplier of spare parts, for complaints etc.);
 - c) description of the product, its technical, using and safety parameters;
 - d) supposed, recommended and prohibited use of and manipulation with the product;
 - e) required qualification of the user, (possibly compulsory) training provided by the manufacturer/supplier/distributor etc.;
 - f) assembling, installation and putting into operation (if in responsibility of the owner/operator/user);
 - g) relations to preceding or following processes, connected/compatible etc. equipment (HW) during use of the product;
 - h) supply of energy and materials;
 - i) outlets of products, emissions, waste etc.;
 - j) cooling/heating/air condition etc.;
 - k) proper using, handling, adjustment, maintenance (in responsibility of the owner/operator/user);
 - l) safety principles for using, adjusting, maintenance, repairs, incl.:
 - la) residual risks and measures for their elimination (see also 9.3.4b);
 - lb) negligible risks (see also 9.3.4c);
 - lc) meaning of safety inscriptions, pictures and pictograms on the product/packaging;
 - ld) use of personal protection equipment, parameters for its consequent purchase;
 - le) and others;
 - m) monitoring of operation and wear and tear, mandatory preventive replacement of parts etc. (see also 9.3.7);
 - n) mandatory use of contracted manufacturer/supplier's service;
 - o) troubles and troubleshooting (in responsibility of the user/operator/owner);
 - p) available repair shops and services, lists of spare parts, their distribution incl. contacts;
 - q) guarantee conditions; exclusion of construction changes (not only loss of guarantee – the original manufacturer is absolved from all his responsibility for the product, and person who made the changes becomes the manufacturer with all consequences (see also definition 029 in Chapter 0, 3.4.9 and Note 2 in 11.5));
 - r) disposal of the product;
 - s) etc.

The list need not be exhaustible and is not limited, some items overlap; the list contains also non-actual items for some products.

11.7 Materials intended for propagation, presentation, training etc. will have rather different character. Nevertheless, even they must correspond to other documentation and reflect the reality.

12 Conclusion

12.1 This publication contains only the **basic principles** which a manufacturer has to follow if he wants to place his products on the market in the EU/EEA (incl. in the Czech Republic).

12.2 Concrete (especially sectoral) legislative acts [A5.6] lay down, for concrete situations and concrete products, details as well as further procedures and differences from the general principles described here. For specific area of construction products, see Appendix 2.

12.3 Due to its restricted extent, this publication cannot cover all specificities of concrete products or types of products. The principles described in the above text are common for various products and manufacturers.

12.4 A much more detailed document is for example the **Blue Guide 2022** [A6.1].

12.5 In the Czech Republic, main source of information for entrepreneurs is the **ÚNMZ Information Portal – “Regulations and Standards”** [A6.2] with outline of monthly updates [A6.2.1].

12.6 In relation with Regulation 1020 [A2.8] aim of which is to eliminate growing amount of non-conforming products, bad traceability of non-conforming products imported into the EU via online means, insufficient border control of imported products etc., a number of new provisions concerning economic operators is being prepared. The economic operators should familiarize themselves with these provisions and their application. Details are outside the scope of this publication.

12.7 A useful source of information for entrepreneurs and public is also the the **ÚNMZ Information Portal “Placing of products on the market”** [A6.15] assembled for ÚNMZ by ITC Zlín, Czech Republic, since July 2022 during the Czech presidency of the EU accessible for free. It is very wide-ranging in areas of placing of products on the market, their conformity assessment, standardisation and standards from various countries, market surveillance, management systems and other useful links. The portal covers not only the area of specified products; its scope is much wider.

12.8 Other recommended **sources of information in the EU:**

- **EUR – Lex** [A1.3] – access to the EU law in all EU official languages;
- **Portal Your Europe** [A6.11] – for orientation of entrepreneurs and citizens in the European legislation and various national legislations of the EU Member States;

as well as the following websites:

- **EU/European Union** [A1.1] – general information;
- **European Commission** [A1.2] – European Commission – Internal Market, Industry, Entrepreneurship and SMEs (GROWTH);
- **EUROLAB** [A1.21] – European Federation of National Associations of Measurement, Testing and Laboratories;
- **EA – European Accreditation** [A1.22];
- **CEOC** [A1.23] – International Confederation of Inspection and Certification Organisations.

Links to information sources

The following links are numbered identically as in the text and in the appendices. The list contains also other links useful chiefly for placing a product on the internal market of the EEA including the market in the Czech Republic. Responsibility for the content of documents linked lies with their owners.

Abbreviations of the links' language versions:

- EU – official version from the EU website, all official languages of the EU (incl. CS) can be chosen;
- CS/EU – ditto opened directly in Czech;
- EN – official version in English;
- CS – official version in Czech;
- EN/CS – both official versions in English (prior) and in Czech can be used;
- CS/EN – both official versions in Czech (prior) and in English can be used;

WARNING: Automatic translation (if allowed in the browser settings) may lead to incorrectness or even faults in terminology. Therefore it is recommended to disable it especially when using the CS/EN or EN/CS links and use only the official versions. A few of the translations in the following list are marked as automatic translation and should be regarded only as informative.

Note: Items marked as “free” are reserved for future or are results of deletion of non actual items.

| No | Name | Address |
|----------|---|---|
| 1 | Institutions, harmonisation in the EU, international organisations | |
| 1.1 | European Union (EN) | EN: http://europa.eu/newsroom/home_en |
| 1.2 | European Commission – Internal Market, Industry, Entrepreneurship and SMEs (EN) | EN: http://ec.europa.eu/growth/ |
| 1.3 | EUR – Lex – website providing access to the EU legislation (EU, CS/EU) | EU: http://eur-lex.europa.eu/ CS/EU: https://eur-lex.europa.eu/homepage.html?locale=cs |
| 1.4 | European Commission website (EN/CS) | EN: https://commission.europa.eu/index_en CS: https://commission.europa.eu/index_cs |
| | free | |
| 1.11 | Internal Market – market of the EU/EEA countries (EN, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:internal_market CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=LEGISSUM%3Ainternal_market |

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| 1.11.1 | Single Market for Goods (EN/CS) | EN: https://ec.europa.eu/growth/single-market/goods_en CS: https://single-market-economy.ec.europa.eu/single-market/goods_en?prefLang=cs&etrans=cs |
| 1.11.2 | CE marking. Internal Market, Industry, Enterprise, Small and Medium Enterprises (EN/CS) | EN: https://ec.europa.eu/growth/single-market/ce-marking_en CS: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en?prefLang=cs&etrans=cs |
| 1.12 | New Approach – principle of directives (EU harmonisation) (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3A114527 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=LEGISSUM:114527 |
| 1.13 | New Legislative Framework (EN/CS – European Commission website / CS – ÚNMZ website) | EN: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en CS: https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en?prefLang=cs&etrans=cs CS: https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/pravni-predpisy/novy-legislativni-ramec/ |
| 1.13.1 | Results of evaluation of the New Legislative Framework (EU, CS/EU) | EU: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12654-Industrial-products-evaluation-of-the-new-legislative-framework_en CS/EU: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12654-Hodnoceni-noveho-legislativniho-ramce-pro-prumyslove-vyrobky_cs |
| 1.14 | Goods Package: Reinforcing trust in the single market (EN, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017DC0787 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A52017DC0787 |
| 1.15 | PCP – Product Contact Points - contact points for free movement of products (EN/CS) | EN: http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/ CS: https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/mutual-recognition-goods/product-contact-points_en?prefLang=cs&etrans=cs |
| 1.15.1 | Enterprise Europe Network Help to innovation and growth (EN) | EN: https://een.ec.europa.eu/ |
| 1.15.2 | Enterprise Europe Network Advice and support (EN) | EN: https://een.ec.europa.eu/content/advice-support |

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| 1.16 | ProCoP – Product Contact Point at Ministry of Industry and Trade of the Czech Republic (CS/EN) | CS: https://www.mpo.cz/cz/zahranicni-obchod/podnikani-v-EU/sluzby-pro-podnikatele-na-vnitrim-trhu-eu/procop/default.htm EN: https://www.mpo.cz/en/foreign-trade/business-in-the-eu/services-for-entrepreneurs-in-the-eu-internal-market/product-contact-point/default.htm |
| 1.17 | Consequences of Brexit (EN/CS) | EN: https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-united-kingdom/new-normal/consequences-brexit_en CS: https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-united-kingdom/new-normal/consequences-brexit_cs |
| | free | |
| 1.21 | EUROLAB aisbl (EN) | EN: https://www.eurolab.org/ |
| 1.22 | EA – European Accreditation (EN) | EN: http://www.european-accreditation.org/ |
| 1.23 | CEOC - International Confederation of Inspection and Certification Organisations (EN) | EN: https://www.iso.org/organization/8898.html |
| 1.24 | Prosafe – European Forum for Safety of Products (EN) | EN: https://www.prosafe.org/ |
| | free | |
| 1.27 | European standards (EN) | EN: https://ec.europa.eu/growth/single-market/european-standards_en |
| 2 | EU legislative acts and documents | |
| 2.1 | Directive 2001/95/EC on general product safety (repealed by Regulation 988, see 2.1.1) (EN/CS) | EN: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:EN:PDF CS: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:CS:PDF |
| 2.1.1 | Regulation 988 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (EU, CS/EU, CS) | EU: https://eur-lex.europa.eu/eli/reg/2023/988/oj CS/EU: https://eur-lex.europa.eu/eli/reg/2023/988/oj?locale=cs CS: https://esipa.cz/sbirka/sbsrv.dll/sb?DR=SB&CP=32023R0988 |

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| 2.1.2 | Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System RAPEX established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334) (consolidated version of 17 May 2023) | EU: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32019D0417 CS/EU: https://eur-lex.europa.eu/legal-content/CS/ALL/?uri=CELEX%3A32019D0417 |
| 2.1.3 | Commission Implementing Regulation (EU) 2024/1435 of 24 May 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards establishing the template for a recall notice (EN/CS) | EN: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401435 CS: https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=OJ:L_202401435 |
| 2.1.4 | Commission Implementing Regulation (EU) 2024/1459 of 27 May 2024 laying down rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the implementation of the interoperable interface of the Safety Gate Portal for providers of online marketplaces (EN/CS) | EN: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401459 CS: https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=OJ:L_202401459 |
| 2.1.5 | Commission Implementing Regulation (EU) 2024/1740 of 21 June 2024 laying down the rules for the application of Regulation (EU) 2023/988 of the European Parliament and of the Council as regards the modalities for consumers and other interested parties to inform the Commission of products that might present a risk to the health and safety of consumers and for the transmission of such information to the national authorities concerned (EN/CS) | EN: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401740 CS: https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=OJ:L_202401740 |
| 2.2 | Regulation 764 Regulation (EC) No 764/2008 (on 19 April 2020 repealed and replaced by Regulation 515 – see 2.6) (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0764 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32008R0764 |
| 2.3 | Regulation 765 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (consolidated text as amended by Regulation 1020 on 16 July 2021– see 2.8) (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R0765 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=celex%3A32008R0765 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=celex%3A32008R0765 |
| 2.4 | Decision 768 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008D0768 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32008D0768 |

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| 2.5 | Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0029 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32013L0029 |
| 2.6 | Regulation 515 Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0515 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32019R0515 |
| 2.6.1 | Guidance document (23 March 2021) for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3A0J.C_.2021.100.01.0016.01.ENG&toc=OJ%3AC%3A2021%3A100%3ATOC CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=uriserv%3A0J.C_.2021.100.01.0016.01.ENG&toc=OJ%3AC%3A2021%3A100%3ATOC |
| 2.7 | Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31985L0374 CS/EU: https://eur-lex.europa.eu/legal-content/CS/ALL/?uri=CELEX:31985L0374 |
| 2.8 | Regulation 1020 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (consolidated version of 23 May 2024) (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32019R1020 |
| 2.9 | Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation ... (EU, CS/EU) | EU: https://eur-lex.europa.eu/eli/reg/2012/1025/oj CS/EU: https://eur-lex.europa.eu/eli/reg/2012/1025/oj?locale=cs |
| 2.10 | Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R0952 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A32013R0952 |
| 2.11 | Directive 2009/104/EC of the European Parliament and of The Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work ... (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0104 CS/EU: https://eur-lex.europa.eu/legal-content/CS/ALL/?uri=CELEX%3A32009L0104 |
| 3 | Organisations and institutions in the Czech Republic (incl. their information systems and databases) | |
| 3.1 | ÚNMZ – Czech Office for Standards, Metrology and Testing (CS/EN) | CS: https://www.unmz.cz/obecne/o-uradu/ EN: https://www.unmz.cz/en/home/ |

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| 3.1.1 | ÚNMZ – list of notified bodies in the Czech Republic (CS) | CS: https://www.unmz.cz/statni-zkusebnictvi/seznam-ao-a-os-uno/ |
| 3.2 | AAAO – Association of Accredited and Authorised Organisations (CS) | CS: http://www.aaao.cz/ |
| 3.2.1 | AAAO – list of AAAO members (CS) | CS: http://www.aaao.cz/clenove/ |
| 3.3 | CAI – Czech Accreditation Institute (CS/EN) | CS: https://www.cai.cz/?page_id=23 EN: https://www.cai.cz/?page_id=12864&lang=en |
| 3.3.1 | CAI – database of subjects accredited by CAI (CS/EN) | CS: https://www.cai.cz/?page_id=4499 EN: https://www.cai.cz/?page_id=12902&lang=en |
| 3.4 | Czech Standardization Agency (CS/EN) | CS: https://www.agentura-cas.cz/ EN: https://www.agentura-cas.cz/en/ |
| 3.4.1 | Public commenting of technical standards (CS) | CS: http://drafts.unmz.cz/ |
| 3.5 | Czech Trade Inspection Authority (CS/EN) | CS: https://www.coi.cz/ EN: https://www.coi.cz/en/ |
| 4 Czech Legal Acts | | |
| 4.1 | Act 22 Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended (CS, EN-working consolidated text of ÚNMZ) | CS: https://www.zakonyprolidi.cz/cs/1997-22/zneni-20210101 CS: https://www.tzb-info.cz/pravni-predpisy/zakon-c-22-1997-sb-o-technicky-pozadavcich-na-vyrobky EN: https://www.unmz.cz/en/office/legislation-in-force/working-consolidated-text-of-act-no-22-1997-coll-on-technical-requirements-for-products/ |
| 4.2 | Act 90 Act No. 90/2016 Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended (CS, EN working translation) | CS: https://www.zakonyprolidi.cz/cs/2016-90/zneni-20240807 EN: https://www.unmz.cz/en/office/legislation-in-force/act-90_16_en_working-translation/ |
| 4.3 | Act 206 Act No. 206/2015 Coll., on pyrotechnics (CS) | CS: https://www.zakonyprolidi.cz/cs/2015-206 |
| 4.4 | Act 102 Act No. 102/2001 Coll., on general safety of products (CS) | CS: https://www.zakonyprolidi.cz/cs/2001-102 |
| 4.5 | Act 263 Act No. 263/2016 Coll., the Atomic Act (CS) | CS: https://www.zakonyprolidi.cz/cs/2016-263 |

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| 4.5.1 | Decrees for implementation of the Atomic Act (Decrees No. 358, 359, 360, 361, 362/2016 Coll.) (CS) | CS: http://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/sb0143-2016.pdf |
| 4.6 | Government Order 173 Government Order No. 173/1997 Coll., that specifies selected products for the conformity assessment, as amended (CS) | CS: https://www.zakonyprolidi.cz/cs/1997-173 |
| 4.7 | Government Order 208 Government Order No. 208/2015 Coll., on technical requirements for pyrotechnical articles and their making available on the market (CS) | CS: https://www.zakonyprolidi.cz/cs/2015-208 |
| 4.8 | Act 87 Act No. 87/2023 Coll., the Market Surveillance Act (CS) | CS: https://www.zakonyprolidi.cz/cs/2023-87 |
| 4.9 | Act 64 Act No. 64/1986 Coll., the Czech Trade Inspection Authority Act (CS) | CS: https://www.zakonyprolidi.cz/cs/1986-64 |
| 4.10 | Act 526 Act No. 526/2020 Coll. amending Act 22 and Act 90 (CS) | CS: https://www.zakonyprolidi.cz/cs/2020-526 |
| 4.11 | Act 634 Act No. 634/1992 Coll., on Consumer Protection (CS) | CS: https://www.zakonyprolidi.cz/cs/1992-634 |
| 4.12 | Act 250 Act No. 250/2021 Coll., on safety of work in connection with operation of special technical equipment (CS) | CS: https://www.zakonyprolidi.cz/cs/2021-250 |
| 5 | | |
| 5 | Product sectors | |
| 5.1 | Specified products (ÚNMZ) [A3.1] (CS) | CS: https://www.unmz.cz/statni-zkusebnictvi/stanovene-vyrobky/ |
| 5.1.1 | Ditto – Harmonised standards by sectors (CS/EN) | CS: https://www.nlnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti EN: https://www.nlnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti |
| 5.2 | Product sectors under Act 22 [A4.1] (CS/EN) | CS: https://www.nlnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2 EN: https://www.nlnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2 |

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| 5.3 | Product sectors under Act 90 [A4,2] (CS/EN) | CS: https://www.nlnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133 EN: https://www.nlnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133 |
| | free | |
| 5.6 | <p>Product sectors For each sector:</p> <ul style="list-style-type: none"> - outline of harmonised standards based on last references in the OJEU (EN/CS); outline of specified standards for selected products - EU harmonisation legislative act (EN/CS); - Czech legislative act (CS); - Slovak legislative act (in Slovak); - link to valid references of harmonised standards in the OJEU (CS); <p><i>Note: For newly established sectors, see end of the list.</i></p> | |
| 5.6.1 | Low voltage equipment (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/89 EN: https://www.nlnorm.cz/en/ehn/kategorie/89 |
| 5.6.2 | Simple pressure vessels (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/105 EN: https://www.nlnorm.cz/en/ehn/kategorie/105 |
| 5.6.3 | Marine equipment (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/184 EN: https://www.nlnorm.cz/en/ehn/kategorie/184 |
| 5.6.4 | Measuring instruments (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/104 EN: https://www.nlnorm.cz/en/ehn/kategorie/104 |
| 5.6.5 | Personal protection equipment (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/210 EN: https://www.nlnorm.cz/en/ehn/kategorie/210 |
| 5.6.6 | Radio equipment (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/193 EN: https://www.nlnorm.cz/en/ehn/kategorie/193 |
| 5.6.7 | Recreational craft and personal watercraft (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/135 EN: https://www.nlnorm.cz/en/ehn/kategorie/135 |
| 5.6.8 | Appliances burning gaseous fuels (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/213 EN: https://www.nlnorm.cz/en/ehn/kategorie/213 |
| 5.6.9 | Pressure equipment (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/195 EN: https://www.nlnorm.cz/en/ehn/kategorie/195 |

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| 5.6.9.1 | Pressure equipment (placed on the market before 19 July 2016) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/110 EN: https://www.nlnorm.cz/en/ehn/kategorie/110 |
| 5.6.10 | Non-automatic weighing instruments (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/103 EN: https://www.nlnorm.cz/en/ehn/kategorie/103 |
| 5.6.11 | Explosives for civil uses (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/97 EN: https://www.nlnorm.cz/en/ehn/kategorie/97 |
| 5.6.12 | Electromagnetic compatibility (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/90 EN: https://www.nlnorm.cz/en/ehn/kategorie/90 |
| 5.6.13 | Lifts (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/109 EN: https://www.nlnorm.cz/en/ehn/kategorie/109 |
| 5.6.14 | Equipment and protective systems intended for use in potentially explosive atmospheres (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/134 EN: https://www.nlnorm.cz/en/ehn/kategorie/134 |
| 5.6.15 | Cableway installations (NLF) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/211 EN: https://www.nlnorm.cz/en/ehn/kategorie/211 |
| 5.6.16 | Aerosol dispensers (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/187 EN: https://www.nlnorm.cz/en/ehn/kategorie/187 |
| 5.6.17 | Ecodesign requirements for household refrigerating appliances (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/113 EN: https://www.nlnorm.cz/en/ehn/kategorie/113 |
| 5.6.18 | Noise emission (NOI) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/186 EN: https://www.nlnorm.cz/en/ehn/kategorie/186 |
| 5.6.19 | Emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/188 EN: https://www.nlnorm.cz/en/ehn/kategorie/188 |
| 5.6.20 | European rail system (high-speed and conventional) (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/112 EN: https://www.nlnorm.cz/en/ehn/kategorie/112 |
| 5.6.21 | Toys (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/85 EN: https://www.nlnorm.cz/en/ehn/kategorie/85 |
| 5.6.22 | Restriction of the use of certain hazardous substances in electrical and electronic equipment (CS/EN) | CS: https://www.nlnorm.cz/ehn/kategorie/93 EN: https://www.nlnorm.cz/en/ehn/kategorie/93 |

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| 5.6.23.1 | Personal protective equipment (placed on the market before 20 April 2019) (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/86 EN: https://www.nlfnorm.cz/en/ehn/kategorie/86 |
| 5.6.23.2 | Personal protective equipment (NLF) (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/210 EN: https://www.nlfnorm.cz/en/ehn/kategorie/210 |
| 5.6.24 | Transportable pressure equipment (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/185 EN: https://www.nlfnorm.cz/en/ehn/kategorie/185 |
| 5.6.25 | Appliances burning gaseous fuels (placed on the market before 21 April 2018) (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/107 EN: https://www.nlfnorm.cz/en/ehn/kategorie/107 |
| 5.6.26 | Construction products CE marked (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/84 EN: https://www.nlfnorm.cz/en/ehn/kategorie/84 |
| 5.6.27 | Machinery (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/106 EN: https://www.nlfnorm.cz/en/ehn/kategorie/106 |
| 5.6.28 | Efficiency requirements for new hot-water boilers (BED) (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/183 EN: https://www.nlfnorm.cz/en/ehn/kategorie/183 |
| 5.6.29 | Medical devices (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/95 EN: https://www.nlfnorm.cz/en/ehn/kategorie/95 |
| 5.6.30 | Active implantable medical devices (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/94 EN: https://www.nlfnorm.cz/en/ehn/kategorie/94 |
| 5.6.31 | In vitro diagnostic medical devices (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/96 EN: https://www.nlfnorm.cz/en/ehn/kategorie/96 |
| 5.6.32 | Pyrotechnic articles (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/100 EN: https://www.nlfnorm.cz/en/ehn/kategorie/100 |
| 5.6.33 | Czech national sector – Selected construction products not CE marked (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_5_vybran.htm |
| 5.6.34 | Czech national sector – Selected products for conformity assessment (CS) | CS: https://www.unmz.cz/urad/vybrane-vyrobky |
| 5.6.35 | EU fertilising products (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/245 EN: https://www.nlfnorm.cz/en/ehn/kategorie/245 |

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| 5.6.36 | Unmanned aircraft systems (NLF) (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/246 EN: https://www.nlfnorm.cz/en/ehn/kategorie/246 |
| 6 Internet portals and databases, information publications | | |
| 6.1 | Blue Guide on the implementation of EU products rules 2022 – Blue Guide 2022 (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOCCS EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=OJ%3AC%3A2022%3A247%3ATOC CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=OJ%3AC%3A2022%3A247%3ATOC |
| 6.2 | ÚNMZ Information Portal – “Regulations and Standards” (CS) | CS: https://www.unmz.cz/urad/informacni-portal-unmz |
| 6.2.1 | Ditto – outline of monthly updates (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/aktualizace.htm |
| 6.3 | OJEU – Official Journal of the EU – quick search (EN, CS/EU) | EU: https://eur-lex.europa.eu/homepage.html?locale=en CS/EU: https://eur-lex.europa.eu/homepage.html?locale=cs |
| 6.3.1 | Statement of the ÚNMZ about revision of harmonised European standards issued by CEN (CS) | CS: https://www.unmz.cz/wp-content/uploads/Zru%C5%A1en%C3%A9-harmonizovan%C3%A9-normy-stanovisko-%C3%9ANMZ.pdf |
| 6.3.2 | Information on the Official Journal (EU, CS/EU) | EUN: https://eur-lex.europa.eu/content/help/oj/about-oj.html CS/EU: https://eur-lex.europa.eu/content/help/oj/about-oj.html?locale=cs |
| 6.3.3 | Browsing of the Official Journal (EU, CS/EU) | EU: https://eur-lex.europa.eu/content/help/oj/browse-oj.html CS/EU: https://eur-lex.europa.eu/content/help/oj/browse-oj.html?locale=cs |
| 6.3.4 | Official Journal daily view (EU, CS/EU) | EU: https://eur-lex.europa.eu/content/help/oj/oj-daily-view.html CS/EU: https://eur-lex.europa.eu/content/help/oj/oj-daily-view.html?locale=cs |
| 6.4 | Database of harmonised standards (CS/EN) | CS: https://www.nlfnorm.cz/normy/475/database-harmonizovanych-norem-477 EN: https://www.nlfnorm.cz/en/normy/475/database-harmonizovanych-norem-477 |

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| 6.5 | Harmonised standards grouped by sectors and areas (CS/EN) | CS: https://www.nlnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti EN: https://www.nlnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti |
| 6.6 | NANDO – New Approach Notified and Designated Organisations – information system of notified bodies. Now incorporated into the SMCS system – see 6.6.1 (EN) | EN: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies |
| 6.6.1 | SMCS – Single Market Compliance Space – combines the New Approach Notified and Designated Organisations (NANDO, see 6.6) and the Noise Emissions by Outdoor Equipment (NOISE) systems (EN) | EN: https://webgate.ec.europa.eu/single-market-compliance-space/#/home |
| 6.6.2 | ÚNMZ note on the integration of NANDO (6.6) into the Single Market Compliance Space (SMCS) portal (6.6.1) (CS) | CS: https://www.unmz.cz/databaze-nando-zmena-v-souvislosti-se-zaclenenim-do-portalu-single-market-compliance-space-smcs/ |
| 6.6.3 | List of Czech notified bodies in NANDO (EN) | EN: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=countryId:203,notificationStatusId:1,bodyTypeId:3 |
| 6.6.4 | List of Czech authorised bodies, notified bodies and recognised third-party organisations on the ÚNMZ website (see 3.1) (CS) | CS: https://www.unmz.cz/statni-zkusebnictvi/seznam-ao-a-os-uno |
| 6.7 | ÚNMZ – Journal of the Office (CS) | CS: https://www.unmz.cz/urad/vestnik-unmz |
| 6.8 | ÚNMZ – Program for Development of Testing (CS) | CS: https://www.unmz.cz/statni-zkusebnictvi/program-rozvoje-zkusebnictvi/ |
| 6.9 | Frequently Asked Questions – Testing (ÚNMZ) (CS) | CS: https://www.unmz.cz/caste-dotazy/casto-kladene-otazky-zkusebnictvi/ |
| 6.10 | Safety Gate – the EU rapid alert system for dangerous non-food products (formerly Rapex database) (EU, CS/EU) | EU: https://ec.europa.eu/safety-gate-alerts/screen/webReport CS/EU: https://ec.europa.eu/safety-gate-alerts/screen/webReport |
| 6.10.1 | Database of dangerous products (Rapex) (CS) | CS: https://www.dtest.cz/nebezpecne-vyrobyky?source=1&utm_source=GoG&utm_medium=p_ravo&utm_campaign=STR_S_DSA&gclid=EAlaIQobChMImqO15_-g-QIVFIXVCh0XwQjcEAYASAAEgLjNvD_BwE |
| 6.11 | Portal “Your Europe” (EU, CS/EU) | EU: https://europa.eu/youreurope/citizens/index_en.htm CS/EU: https://europa.eu/youreurope/citizens/index_cs.htm |
| 6.12 | Portal “Zákony pro lidi” (“Laws for people”) (CS) | CS: https://www.zakonyprolidi.cz/ |
| 6.13 | Portal “Esipa” (CS) | CS: https://esipa.cz/ |
| 6.14 | Portal of Czech public administration (CS) | CS: https://www.mvcr.cz |

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| 6.15 | ÚNMZ Information Portal – “Placing of products on the market” (CS) | CS: https://www.nlfnorm.cz/informacni-portal |
| 6.16 | Information system for implementation of EU legislation (CS) | CS: https://isap.vlada.cz/homepage.nsf/verejnost |
| 6.17 | Authorities responsible for implementation of EU legislation into the Czech legislation – central authorities of the Czech Republic (CS) | CS: https://isap.vlada.cz/dul/dirtaiii.nsf/gestor?OpenView |
| 6.18 | Commission decisions based on objections against publication of harmonised European standards in the OJEU (EN) | EN: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/formal-objections_en |
| 7 Harmonisation outside the specified products | | |
| 7.1 | Horizontal legislative acts – NLF (CS/EN) | CS: https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=3 EN: https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=3 |
| 7.2 | General product safety (CS/EN) | CS: https://www.nlfnorm.cz/ehn/kategorie/87 EN: https://www.nlfnorm.cz/en/ehn/kategorie/87 |
| 7.3 | Other selected sectors (CS/EN) | CS: https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=5 EN: https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=5 |
| 7.4 | Services (CS/EN) | CS: https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=105 EN: https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=105 h |
| 7.5 | Accessibility of websites and mobile applications (CS/EN) | CS: https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=217 EN: https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=217 |
| 7.6 | EU harmonisation legislative acts WITHOUT issued harmonised European standards (CS/EN contacts) | CS: http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/sek_tor_dalsi%20_22.htm EN kontakts: https://www.unmz.cz/en/home/ |
| 7.7 | Specified Czech standards (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/neh_en.htm |
| 7.8 | ECO – regulations and standards for ecodesign and energetic labels of appliances (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/eko.htm |

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| 7.9 | REACH – Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (EN/CS) | EN: https://osha.europa.eu/en/themes/dangerous-substances/reach CS: https://osha.europa.eu/cs/themes/dangerous-substances/reach |
| 8 Construction products | | |
| 8.1 | ÚNMZ Information Portal for Construction Products (CS/EN) | CS: https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/informacni-portal-unmz-specializovany-na-pravni-a-technicke-dokumenty-v-oblasti-uvadeni-stavebnich-vyroby-na-jednotny-evropsky-trh-c233/ EN: https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/information-portal-construction-products/ |
| 8.1.1 | Ditto – outline of monthly updates (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/aktualizace.htm |
| 8.2 | CPR Regulation (EU) No 305/2011 – Construction Products Regulation (consolidated version with amendments of 16 July 2021 by Regulation 1020) (EU, CS/EU) | EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0305-20210716 CS/EU: https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX%3A02011R0305-20210716 |
| 8.2.1 | Draft review of 10 April 2024 of Construction Products Regulation (EU, CS/EU) (CS – information of the ÚNMZ) (CS – ÚNMZ portal) | EU: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0188_EN.html CS/EU: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0188_CS.html CS/ÚNMZ: https://www.unmz.cz/nove-narizeni-o-stavebnich-vyrobcich-2/ CS/ÚNMZ http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_3_cpr_revize.htm |
| 8.3 | Database of harmonised European standards / harmonised Czech standards to the CPR (CS/EN) | CS: https://www.nlfnorm.cz/normy/70/prehled-harmonizovanych-norem-k-cpr EN: https://www.nlfnorm.cz/en/normy/70/prehled-harmonizovanych-norem-k-cpr |
| 8.4 | Database of European Assessment Documents (EAD) to the CPR (CS/EN) | CS: https://www.nlfnorm.cz/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr- EN: https://www.nlfnorm.cz/en/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr- |

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| 8.5 | Groups of harmonised standards and EAD's according to Annex IV of the CPR (CS/EN) | CS: https://www.nlnorm.cz/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku EN: https://www.nlnorm.cz/en/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku-podle-prilohy-iv-k-cpr |
| 8.6 | Government Order 163 Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products, as amended (amendments by Government Order No. 119/2024 Coll.(see 8.6.1) in force from 1 January 2025 are not incorporated) (CS) | CS: https://www.zakonyprolidi.cz/cs/2002-163 |
| 8.6.1 | Government Order 119 Government Order No. 119/2024 Coll., amending Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products (in force from 1 January 2025) (CS) | CS: https://www.zakonyprolidi.cz/cs/2024-119 |
| 8.7 | Specified standards to Government Order 163 (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/tech_poz/cr/pp_cr/vybr_stav/un_163_2002/un_163_2002.htm |
| 8.8 | Technical guides to Government Order 163 (CS) | CS: http://koordinacesv.tzus.cz/technicke-navody |
| 8.9 | EU brochure “CE marking of construction products step by step” (EN/CS) | EN: https://ec.europa.eu/docsroom/documents/12308/attachments/1/translations/en/renditions/native CS: http://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/CE-marking_CS_150622%20final.pdf |
| 8.10 | CPCP – Contact point for CE-marked construction products (harmonised and non-harmonised) according to Regulation (EU) No 305/2011 (CPR) (EN/CS) | EN: https://www.mpo.cz/en/construction-and-raw-materials/contact-point-for-construction-products/product-contact-point-for-construction--147314/ CS: https://www.mpo.cz/cz/stavebnictvi-a-suroviny/kontaktmi-misto-pro-stavebni-vyrobky/kontaktmi-misto-pro-stavebni-vyrobky-s-oznaceni-ce-podle-narizeni-c--305-2011-eu--o-stavebnich-vyrobcich--147227/ |
| 8.11 | Information from the Coordinating institute in the field of construction products authorized by the ÚNMZ (CS) | CS: http://koordinacesv.tzus.cz/koordinacni-pracoviste |
| 8.12 | Technical assessment bodies (TABs) in the EU (incl. the Czech Republic) (EN) | EN: https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notified-body-list?filter=bodyTypeId:3,legislationId:33 |
| 8.12.1 | Notified Bodies (CPR) and Technical assessment bodies (TABs) in the Czech Republic (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=unmz/nv190/no_190.htm |

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| 8.12.2 | Bodies authorised for conformity assessment activities for selected construction products under Government Order 163 (CS) | CS: http://www.sgpstandard.cz/editor/unmz/?u=unmz/nv163/polozky/ao163.htm CS: https://ppv.zkusebnictvi.cz/stanovene-vyrobky-detail-21-cz.html |
| 8.13 | ETA – European technical assessment (EN, CS) | EN: https://www.eota.eu/what-is-an-eta CS: http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_7_eta.htm |
| 8.14 | EAD – European assessment document (EOTA) (EN) | EN: https://www.eota.eu/what-ead |
| 8.15 | Mutual recognition – obligations of distributors making available non-harmonised construction products in the Czech Republic (document of Ministry of Industry and Trade of the CR, Ministry of Regional Development of the CR, Czech Trade Inspection Authority, ÚNMZ, Technical and Test Institute for Construction Prague) (CS) | CS: https://www.mpo.gov.cz/assets/cz/stavebnictvi-a-suroviny/kontaktmi-misto-pro-stavebni-vyrobky/2020/4/Stavebni-vyrobky---vzajemne-uznavani_1.pdf |

End of Annex A

Identification of changes of EU and Czech legislative acts

The changes concern horizontal topics of this publication.

The table includes EU harmonisation legislative acts and Czech legislative acts in force as well as their revisions (both expected and under way).

Selected links to information sources are listed in Annex A.

The following table reflects changes of legislation done between years 2023 (after 31 July 2023) and 2024 (ca by 31 July 2024).

| Item | Basic legislative acts regulating placing of products on the market | Main changes <i>Current state of legislative acts</i> – see the ÚNMZ Information Portal “Regulations and Standards” [A6.2] and outline of monthly updates [A6.2.1] |
|------|---|--|
| 1 | NLF – Regulation 764 [A2.2] | repealed |
| 2 | Regulation 515 [A2.6] | Regulation 515 [A2.6]. <i>Unchanged</i> |
| 2.1 | Guidance to Regulation 515 [A2.6.1] | Guidance document (dated 23 March 2021) for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State <i>Unchanged.</i> |
| 3 | NLF – Regulation 765 as amended [A2.3] | <i>Amended on 16 July 2021 – partly repealed and replaced with Regulation 1020 [A2.8] – see Item 4</i> |
| 4 | Regulation 1020 [A2.8] | N 1020 [A2.8] Amendments by Regulation 2023/1542 (batteries) and Regulation 2024/1252 (supply of critical raw materials) |
| 5 | NLF – Decision 768 as amended [A2.4] | Decision 768 [A2.4] <i>Unchanged.</i> |
| 6 | Other EU horizontal harmonisation legislative acts | Following the issue of harmonisation legislative acts mentioned in Items 2 and 4, changes in the horizontally applicable legislative acts are announced – Items 10, 11 below. Concurrently some directives or regulations (EU) concerning concrete product sectors are being amended or completed (not within the scope of this publication). See also Item 9 below. |
| 7 | Act 22 – Act No. 22/1997 Coll. as amended [A4.1] | Following the issue or update of EU harmonisation legislative acts (including sectoral acts) affecting Act 22, Act 22 is being correspondingly updated. For details, see [A4.1]. |
| 8 | Act 90 – Act No. 90/2016 Coll., as amended [A4.2] | Following the issue or update of EU harmonisation legislative acts (including sectoral acts) affecting Act 90, Act 90 is being correspondingly updated. For details, see [A4.2]. |
| 9 | Government | Update on (sectoral) harmonisation legislative acts and relevant harmonised |

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| | orders implementing Act 22 and Act 90 | standards – see (in Czech) http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/aktualizace.htm Reduction of harmonised sectors to Act 22 – concerns the sectors transferred to Act 90. and new sectors harmonised to Act 90. Updates on national Czech government orders not harmonised with the EU. <i>(All these changes are reflected in the links (Annex A), if they have any impact on the publication's text.)</i> |
| 10 | Regulation 988 on general product safety [A2.1.1] | Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC – Regulation 988 [A2.1.1]. Regulation 988 reflects changes on the market with products and updates the legal framework for general safety of non-food products. Continuity with the current legislation is ensured. Regulation 988 shall apply from 13 December 2024 when Directive 87/357/EEC and Directive 2001/95/EC will be repealed. Three Commission Implementing Regulations have been issued concerning the Safety Gate: 2024/1435 (recall notice) [A2.1.3]; 2024/1459 (online marketplaces) [A2.1.4]; 2024/1740 (information procedures) [A2.1.5]. |
| 10.1 | Act 102 Act No. 102/2001 Coll., on general safety of products [A4.4] | Implementation of Regulation 988 into the Czech legislation (amendment/replacement of Act 102 [A4.4]) is under preparation. Published draft of the act following the regulation on general product safety defines the institutional scheme of surveillance of product safety in the Czech Republic which will be united with market surveillance of products from harmonised sphere. Last step: 7 March 2024 – deadline for comments |
| 11 | Act 87 – the Market Surveillance Act [A4.8] | Act No. 87/2023 Coll., the Market Surveillance Act [A4.8] entered into force on 6 April 2023. The Act implements into the Czech legislation Regulation (EU) 2019/1020 [A2.8] of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 [A2.3] and (EU) No 305/2011 [A8.2]. <i>Act 22 [A4.1], Act 90 [A4.2] and Act 102 [A4.4] are amended by Act 87.</i> See also Item 10.1. <i>This publications mentions obligations of economic operators concerning their cooperation with market surveillance authorities and realisation of measures resulting from the surveillance. Details of market surveillance are not in scope of this publication.</i> |
| <i>End of Appendix 1</i> | | |

Specific features of construction products

This publication does not cover the area of construction products because of (a.o.) their specific features, some general examples being as follows:

- the “harmonised” area is currently regulated by Regulation (EU) No 305/2011 – Construction Products Regulation – **CPR** [A8.2] (see definition 014 in Chapter 0);
- harmonised technical specifications for the CPR are **harmonised European standards** (see the database in [A8.3]) and **European Assessment Documents (EAD)**, see the EAD database in [A8.4];
- for products to which a harmonised European standard does not exist but EAD’s do, a “technical assessment body” (TAB) [A8.12]/[A8.12.1] may be asked to issue a “**European Technical Assessment – ETA**” [A8.13];
- modules used in other sectors (Decision 768, Annex II) [A2.4] are not used in the CPR; “**systems of assessment and verification of constancy of performance**” (AVCP) are used, called 1, 1+, 2+, 3, and 4;
- in the “harmonised” area, the manufacturer does not issue an “EU/EC declaration of conformity” but a “**Declaration of performance**”;
- for all construction products to which a harmonised European or Czech standard applies or for which an ETA has been issued, the **CE marking is the only marking**; it declares that the construction product is in **conformity** with performance stated in the “**Declaration of performance**” issued by the manufacturer in relation to essential characteristics according to the harmonised European or Czech standard or the ETA in question;
- affixing of the **CE marking is then obligatory** for all construction products for which the manufacturer has drawn up the “Declaration of performance”;
- **different** definitions with different meaning are used (e.g. essential characteristics, performance, levels, classes, threshold levels, product type, intended use etc.). Basic **principles** for making available / placing on the market are **analogous**;
- not only characteristics of a product itself but especially its influence on fulfilling the **basic requirements for the construction work** in which it has to be installed is taken into account; only such construction product can be placed on the market whose performances (after its correct installation in the construction work) do not represent risk for fulfilling the basic requirements for the construction work;
- the CPR underwent substantial revision. On 10 April 2024, the European Parliament approved the text of a new regulation [A8.2.1]. Formal procedures leading towards the official publication follow;
- publication in the Official Journal of the EU is supposed in Autumn 2024;
- the new regulation will maintain and deepen some current principles but also introduce some new ones;
- the transitional period will be 15 years from entry into force of the new regulation (i.e until 2039);
- during this period, corresponding changes are to be expected in the Czech legislation;
- products without any harmonised European or Czech standard applicable to them are in the “non-harmonised” area and are regulated by national regulation of the EU Member States;
- in the Czech Republic, the national regulation for the **non-harmonised area** is represented by **Government Order 163** [A8.6] issued for implementation of Act 22 [A4.1];
- in the Czech Republic, **specified technical standards** [A8.7] and **technical guides** [A8.8] serve as technical specifications for Government Order 163;
- even in the “non-harmonised” area in the Czech Republic there are specific conformity assessment procedures laid down in Government Order 163 [A8.6], sections 5 to 12;

- if required by the concrete procedure, relevant documents for a declaration of conformity have to be obtained from the **authorised body** [A8.12.2];
- the manufacturer issues the **declaration of conformity** after finishing the conformity assessment procedure;
- Government Order 119 [A8.6.1] amending Government Order 163 [A8.6], in force from 1 January 2025, lays down obligation for manufacturers or importers to declare in the issued declaration of conformity the performance in scope of the initial type test (represented by class, level, threshold level or description so as the construction work could be properly designed and realised). Then the manufacturer has to affix the Czech conformity mark to the product according to the annex of this government order;
- for mutual recognition of construction products, the document of Ministry of Industry and Trade of the CR, Ministry of Regional Development of the CR, Czech Trade Inspection Authority, ÚNMZ, Technical and Test Institute for Construction Prague “Mutual recognition – obligations of distributors making available non-harmonised construction products in the Czech Republic” [A8.15] can be used;
- for further details, see the ÚNMZ Information Portal – “Construction Products” [A8.1] + outline of monthly updates [A8.1.1];
- the European Commission published an **information brochure** “CE marking of construction products step by step” [A8.9] containing a.o. many links to other information sources;
- further information can be seen on the website of the **Coordinating institute** [A8.1] in the field of construction products authorized by the ÚNMZ [A3.1];
- information sources for the sector of construction products are listed in Chapter 8 of Annex A;

More specific features are possible.

End of Appendix 2

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