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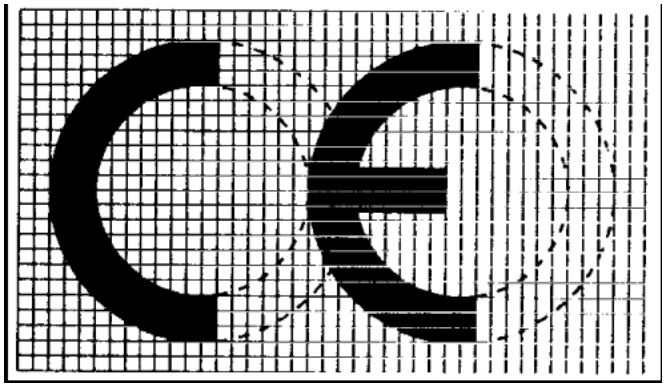


Placing of products on the Internal Market of the European Economic Area

Services of testing, inspection and certification bodies of the Czech Republic – an EU Member State – for manufacturers from third countries

Version 2020

This document is addressed to manufacturers from countries outside the European Economic Area (EEA) as well as to importers of their products to the EEA and authorised representatives established within the EEA, especially those established in the Czech Republic.
In the Czech Republic, it can be helpful also to manufacturers, staff members of notified bodies and recognised third-party organisations, and national authorities and expert public.
The rules described in the following text apply only to products whose conditions for placing on the EEA internal market are regulated by **EU harmonisation acts of the so called New Approach.** They are currently being completed and replaced by **EU harmonisation acts (directives, regulations) of the so called New Legislative Framework.** Legislative acts of the so called „**Goods Package: Reinforcing trust in the single market**" are also being implemented.
In the Czech Republic, these provisions apply also to selected products placed on the market in accordance with the Czech national legislative acts not harmonised with EU legislation.

Contents:

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 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*** *used in the text.*

Introduction

Supported by the Czech Office for Standards, Metrology and Testing – **ÚNMZ** – (A3.1) + English version (A3.1.1) + Russian version (A3.1.2) under the Standardisation Plan – Program for Development of Testing – the Association of accredited and authorised organisations **AAAO** (A3.2) issued in 2013, 2016, and 2018 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**) (A1.10). In 2015, 2017, and 2019, publications with the same subject matter and updated text were issued for economic operators in the Czech Republic.

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 conformity with the essential requirements of the relevant legislation acts has been assessed.

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.

In the Czech Republic, the rules described in the following text apply to products which we call in this publication **"specified products"**, which are

a) products to which government orders implementing Act **No. 22/1997** Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended (hereinafter **Act 22**) (A4.1) + English version (A4.1.1) as well as other legislative acts (for example act on medical devices) apply. These products include also products regulated by national Czech government orders for selected products (A4.6) and for selected construction products (A4.7) and practically also products regulated by the Atomic Act (A4.5) and its implementing legislative acts (A4.5.1);
b) products to which Czech government orders implementing Act **No. 90/2016** Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended (hereinafter **Act 90**) (A4.2) + English version (A4.2.1) apply;
c) products to which Act No. 206/2015 Coll., on Pyrotechnic Products and the Handling of Pyrotechnic Products and on the Amendment to Certain Acts (Pyrotechnics Act), as amended (hereinafter Act 206) (A4.3) with implementing government orders (A4.8) applies;
d) products to which **directly applicable EU harmonisation legislative acts** in the area of placing of products on the market apply (these regulations are adapted by either **Act 22** (A4.1) or **Act 90** (A4.2) or **other** Czech legislative acts);

This publication describes only the **basic principles** which the manufacturer should not ignore when placing his products on the internal market in accordance with the legislative acts. Further details can be found in the information sources mentioned in the publication (repeatedly, if appropriate). As these sources including information contained are subject to changes, their **up-to-date version** should always be used.
Specific conditions for placing of ***construction products*** *on the internal market* ***is not dealt with in detail*** *by this publication – only basic information on differences are mentioned.*

0 Selected basic terms and abbreviations

01 ČR – Czech Republic, Member of the EU;

02 European Economic Area (EEA) – consists of the EU Member States (since 2013 incl. Croatia, since February 2020 (see the next Note) without the United Kingdom of Great Britain and Northern Ireland (hereafter the United Kingdom)) and Liechtenstein, Norway, and Iceland.

***Note**: Since 1 February 2020, the United Kingdom has withdrawn from the European Union. The Withdrawal Agreement provides for a transition period ending on 31 December 2020. As of 1 January 2021 the United Kingdom will be regarded as "a third country" with all consequences (for example, the Notified Bodies currently established in the United Kingdom will lose their NB status and their outputs will no longer be usable for placing products on the internal market). The economic operators concerned should therefore consider very carefully the impact of this change of legal situation and take appropriate actions. For more information concerning the product sectors, see the European Commission website https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/getting-ready-end-transition-period_en.*

03 Internal market (A1.10) – the market of the EU/EEA states to which a.o. free movement of products applies (1.4); in the frame of the Custom Union Agreement the rules for free movement of products also enclose Turkey;

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);*

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 act with common regulation:

- either **directly applicable** (regulations), or
- **transposed** in all Member States (from 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 § 13b of the Act 22) can be regarded as **equivalent**; since 19 April 2020, eventual problems have been solved in accordance with **Regulation 515** (A2.14 + English version A2.14.1), not Regulation 764 – see also 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 the 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 (NA) – 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;

09 Presumption of conformity – the basic principle of the New Approach - fulfilling of the relevant requirements of a harmonised standard/specification is considered to be fulfilling of corresponding (essential) requirements of the legislative act;

010 New Legislative Framework (NLF) (A2.4) – the result of so called "revision of the New Approach" in the years 2005-2008; consisting of the following legislative acts:

- Regulation 515 (A2.14) + English version (A2.14.1) – in force since 19 April 2020, replaces Regulation 764 (see definition 011.1);
- Regulation 765 (A2.6) (as of 16 July 2021, it will be changed by Regulation 1020 (A2.16));
- Decision 768 (A2.4) + English version (A2.4.1);

011 Regulation 764 (repealed from 19 April 2021 – see definition 011.1) – Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (A2.5);
*(This was one of **directly applicable** EU legislative acts in the Czech Republic.)*

011.1 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 (A2.14);
*(This is one of **directly applicable** EU legislative acts in the Czech Republic.)*
(New legislative act – 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. This regulation is directly applicable to all Member States (A2.6);
*(This is one of **directly applicable** EU legislative acts in the Czech Republic.)*
Amendments (incl. title) by Regulation 1020 (A2.16), Article 39 will enter into force on 16 July 2021. 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 (A2.16);
*(This is one of **directly applicable** EU legislative acts in the Czech Republic.)*
(New legislative act – in force from 16 July 2021, some articles from 1 January 2021.)

***Note 1**: New draft of Czech market surveillance act (A4.9) is being prepared implementing this regulation – see Appendix, Items 4 and 15.*

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 (A2.7);

014 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 (A2.8);
*(This is one of **directly applicable** EU legislative acts in the Czech Republic.)*
Amendments of Article 56 by Regulation 1020 (A2.16), Article 40 will enter into force on 16 July 2021.

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; it implements the New Approach principles into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **before** implementation of the New Legislative Framework (except for the Toys' safety Directive which is harmonised with its principles) (A4.1) + English version (A4.1.1);;

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; it implements principles of the New Legislative Framework (especially using Decision 768 (A2.7)) into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **in compliance with** the New Legislative Framework (A4.2) + English version (A4.2.1);

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

018 Conformity assessment

- according to Decision 768/Act 90 (A2.7/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 (A2.12) + English version (A2.12.1) – 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 (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 (A2.12) – a body performing activities concerning conformity assessment procedures laid down in valid technical harmonisation legislative acts, if involvement of a third party is required;

020 Notified body – a legal entity notified according to the relevant piece of EU New Approach legislation and listed in the **NANDO** database (A2.11). It is notified by an EU/EEA Member State (also by the Czech Republic) for conformity assessment activities (testing, inspection, certification) at which its involvement is required or enabled by the relevant EU New Approach harmonisation legislation.
When listed in NANDO, the notified body is entitled to act in the whole EU/EEA.

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

Note 1*: the scope of the notification is specified for a product (product group), a legislative act and a module/assessment procedure with possible further specification;*

Note 2*: the scope of the notification of different bodies is different, scopes of their activities overlap;*

Note 3*: the notified bodies compete on the conformity assessment market (both in the Czech Republic and in the EEA);*

021 hEN – harmonised European standard;

022 hČSN – in the Czech Republic only – harmonised Czech standard;

023 uČSN – in the Czech Republic only – 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 – Czech Standardization Agency (a state contributory organization established by the ÚNMZ) (A3.5) + English version (A3.5.1);

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:

- **Government Orders** issued in the past for implementation of **Act 22** (A4.1);
- incl. 2 national Government Orders for selected products in the Czech Republic (A4.6, A4.7);
- incl. the Atomic Act (A4.5) and its implementing regulations (A4.5.1);
- **Government Orders** issued for implementation of **Act 90** (A4.2);
- **directly applicable** EU legislative acts concerning placing products on the market;
- **or separate acts** implementing into the Czech legislation EU harmonisation documents concerning placing products on the market (e.g. Act on pyrotechnics (A4.3));

027 Making available on the market – any supply of a 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 (A2.7) and as of 16 July 2021 similarly according to Regulation 1020 (A2.16));

028 Placing on the market – the first making available of a product on the market (according to Decision 768 (A2.7) and as of 16 July 2021 similarly according to Regulation 1020 (A2.16));

***Note**: 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...;*

029 Economic operators

- according to Decision 768 (A2.7) – the manufacturer, the importer, the distributor, and the authorised representative;
- according to Regulation 1020 (A2.16) (see definition 012.1 above) – 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;

***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 (A2.7) – 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;
- as of 16 July 2021 according to Regulation 1020 (A2.16) – 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;

***Note**: The term **manufacturer** covers in this publication – in accordance with some harmonisation EU/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 (A2.7) – any natural or legal person who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- as of 16 July 2021 according to Regulation 1020 (A2.16) – any natural or legal person who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant EU harmonisation legislation or under the requirements of Regulation 1020;

032 Importer – established within the EU – any natural or legal person who places a product from a **third country** (outside the EU) (according to Decision 768 (A2.7) and as of 16 July 2021 similarly according to Regulation 1020 (A2.16));

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 (A2.7) and as of 16 July 2021 similarly according to Regulation 1020 (A2.16));

034 Fulfilment service provider – as of 16 July 2021 (according to Regulation 1020 (A2.16)) – 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 – as of 16 July 2021 (according to Regulation 1020 (A2.16)) – any natural or legal person residing or established in the Union, 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 (A2.7));

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 (A2.7));

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 (A2.7));

039 Non-compliance – as of 16 July 2021 (according to Regulation 1020 (A2.16)) – any failure to comply with any requirement under the Union harmonisation legislation or under Regulation 1020;

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

041 Online interface – as of 16 July 2021 (according to Regulation 1020 (A2.16)) – 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 "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.
The concept of manufacturer according to the EU harmonisation legislation based on the New Legislative Framework (A2.4) is different from the concept of manufacturer in Directive 85/374/EEC concerning liability of consumer products (A2.15) + in other EU languages (A2.15.1).

***Note 2**: Some EU harmonisation legislation 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 (A2.16) (see 012.1 above) for fulfilment service providers.

*Specific features of **construction products**: the general principle is analogous. Unlike in other product sectors, not only inherent qualities of the product itself are taken into account for construction products. In addition, also the influence of the construction product on meeting the basic requirements for **construction works** in which the product is to be used is taken into consideration. As a result of this, only such a construction product can be placed on the market whose qualities (after its proper incorporation into the construction works) do not pose a **risk** for meeting the basic requirements for **construction works**. For details, see the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1), monthly updates (A6.2.2).*

*In the Czech Republic, a draft of an **act on construction products and their use in construction works** is being prepared, with presumed entry into force in 2022. Its main principles are: unification of rules for harmonised and non-harmonised areas, requirements for surveillance of construction products delivered directly to the building site and to storage spaces intended for construction works. Government Order No. 163/2002 Coll. (A4.6) will be repealed and two new legal acts will be issued implementing the new act.*

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;
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);
c) **delegated acts** adopted by the European Commission according to relevant provisions and duly notified to the European Parliament and the Council;

The European Commission publishes also **interpretative** documents – not binding 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 (A2.16), as of 16 July 2021 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) + English version (A4.1.1) based on principles of the New Approach, and **Act 90** (A4.2) + English version (A4.2.1) based on the principles of the New Legislative Framework, and **Act 206** (A4.8).
These principles cover sectors (areas) listed in **Annex B** of this publication, the current state can be followed in the **ÚNMZ Information Portal** (A6.1) in the following sections:

a) product areas (sectors) to **Act 22** (A5.2) + English version (A5.2.1);
b) product areas (sectors) to **Act 90** (A5.3) + English version (A5.3.1).

In addition to products from the above mentioned sectors (areas), in the Czech Republic products from the **non-harmonised area** are also covered by **Act 22**, see 2.8 and **Annex B** of this publication.

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 respective Member State. Problems

with application of technical and administrative requirements of other Member State (which in the past were solved by Regulation 764 (A2.5)) are as of 19 April 2020 solved by Regulation 515 (A2.14). According to it, it is possible to draw up to a "Declaration of lawful marketing of goods for the purposes of mutual recognition" (mutual recognition declaration), which demonstrates to the competent authorities of the Member State of destination that the product in question has been lawfully placed on the market in another Member State. The mutual recognition declaration shall contain all the information specified in Part I and Part II of the Annex to Regulation 515 as well as follow the laid down structure of the information. Where the product for which the mutual recognition declaration is being supplied is also subject to an EU act requiring an EU declaration of conformity, the mutual recognition declaration may be attached to the EU declaration of conformity. The mutual recognition declaration shall be drawn up in one of the official languages of the EU, possibly with translation into a language required by the Member State of destination.

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 Czech legislative acts transposing the EU harmonisation legislative acts including directly applicable acts – EU regulations (if they exist);
b) if he places his product on the market in another Member State, he applies the directly applicable EU harmonisation legislative acts 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 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 "on **General Product Safety"** (the General Product Safety Directive or the GPSD (A2.1) **+** English version (A2.1.1)).

The GPSD is transposed into the Czech legislation by 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). This Act relates to the 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 legislative act or a Member State's (e.g. Czech Republic's) law.

Note: *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 not imposed by the directive or the EU directly applicable regulation.*

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 concerning the directives, see the **Guide** to the implementation of directives based on the New Approach and the Global Approach (A2.3) + English version (A2.3.1).

2.3 The EU harmonisation legislative acts based on the New Approach 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 to fulfilling of them are included in **harmonised technical specifications**, mainly in **harmonised European standards**.

Note: *The basic principles are in force also for placing on the market of* ***construction products*** *although some partially specific rules apply. 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 (the* ***Construction Products Regulation*** *–* ***CPR****) (A2.8) + English version (A2.8.1), came fully into force on 1 July 2013. (As of 16 July 2021, the CPR will be amended by Regulation 1020 (A2.16).) In the CPR, harmonised technical specifications include (in addition to harmonised standards) also European Assessment Documents (****EAD****) (A6.9.2) – for details, see the ÚNMZ Information Portal – Construction Products (A6.2) + English version (A6.2.1), monthly updates (A6.2.2).*

The specific rules derived from the CPR result from the definition of "construction products" as products which are produced and placed on the internal market for ***incorporation in a permanent manner in construction works*** *or parts thereof.*

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 was revised and documents representing the "**New Legislative Framework**" (NLF) (A2.4) + English version (A2.4.1), adopted. 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** (A2.14) + English version (A2.14.1), since 19 April 2020 replacing Regulation (EC) No 764/2008 (**Regulation 764**) (A2.5) + English version (A2.5.1);
- Regulation (EC) No 765/2008 of the European Parliament and of the Council (hereinafter **Regulation 765**) (A2.6) + English version (A2.6.1) – in 2021 the title will be changed and some parts replaced by Regulation 1020 (A2.16) + English version (2.16.1);
- Decision No 768/2008/EC of the European Parliament and of the Council (hereinafter **Decision 768**) (A2.7) + English version (A2.7.1).

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 regulations (at this time for example the Construction Products Regulation, the Cableways Regulation, the Personal Protective Equipment Regulation, the Gas Appliances Regulation, Regulation on emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, European railway system, refrigerating appliances, three regulations in the sector of medical devices).

The base for all these changes is Decision 768 (A2.7) + English version (A2.7.,1). Hitherto different texts in some parts of the directives are being substituted with reference provisions of Decision 768. The recast does not concern essential requirements; their eventual change would be subject of planned full revision of the relevant directive.

Note 1*: Decision 768 (A2.7) 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).*

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** (A6.1):

- the product areas (sectors) under **Act 22 (A5.2) +** English version (A5.2.1);
- the product areas (sectors) under **Act 90 (A5.3) +** English version (A5.3.1).

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 (A4.7).

For placing on the internal market of these products as well as for their distribution, **Regulation 764** also applied (A2.5) + English version (A2.5.1) – since 19 April 2020, this regulation has been repealed and replaced with **Regulation 515** (A2.14) + English version (A2.14.1);

2.9 Some NLF directives may be transposed into the Czech government orders implementing other laws than **Act 90** (A5.3) or **Act 22** (A5.2) (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 (A2.9) + English version (A2.9.1).

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 placing of such products on the internal market are derived from those legislative acts and often differ from the rules described in this publication. 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 enjoyed the guarantee of **free movement** within the internal market on conditions laid down by those legislative acts and **Regulation 515** (A2.14) + English version (A2.14.1), since 19 April 2020 replacing repealed **Regulation 764** (A2.5) + English version (2.5.1).
Regulation 1020 (A2.16) (effective on 16 July 2021, some articles on 1 January 2021) will introduce new provisions for placing of such products on the market 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 are 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**: Possible problems with free movement of such products within the internal market were solved in **Regulation 764** (A2.5) + English version (A2.5.1) which was repealed on 19 April 2020 and replaced with **Regulation 515** (A2.14) + English version (A2.14.1).*
*In doubt, the service of the **Product Contact Points** (A1.9) 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 (A2.14).*
*In the Czech Republic, the **Product Contact Point (ProCoP)** is currently established under the umbrella of Ministry of Industry and Trade (A3.3a) or (A.3.3b).*

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) is obliged to ensure in the frame 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** (A2.7) + English version (A2.7.1):
- obligations of manufacturers (R2);
- obligations of authorised representations (R3);
- obligations of importers (R4);
- obligations of distributors (R5).

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

3.1.4 Without prejudice to any obligations of economic operators laid down in the relevant EU legislative acts, Regulation 1020 (A2.16) (effective on 16 July 2021, some articles on 1 January 2021) 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.

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

3.2.1 Obligations of **manufacturers** apply also to subjects established outside the EU and are practically identical with those of manufacturers established within the EU. 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 the EC/EU declaration of conformity;

- identification of the product and the manufacturer on/at the product (to ensure the product's traceability);
- 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;
- tests of products prior to their placing on the market or putting into service (at mass or repeated production);
- corrective measures for non-conformed products, recall, withdrawal;
- evidence of complaints and of recalled products;
- informing of distributors;
- informing of market surveillance authorities;
- cooperation with market surveillance authorities;
- right to appoint an authorised representative.

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 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 the specified products in the EU/EEA countries.

3.2.5 As of 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 (A2.16).

3.2.6 As of 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 (A2.16).

3.3 The New Legislative Framework 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** all economic operators
a) they bought the product from (their suppliers), and
b) whom they supplied the product to (their customers).

*Specific features of **construction products**: Obligations of economic operators are described directly in the **CPR** (A2.8) + English version (A2.8.1):*

- *obligations of manufacturers (Article 11);*
- *obligations of authorised representatives (Article 12);*
- *obligations of importers (Article 13);*
- *obligations of distributors (Article 14).*

*For details, see the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1), monthly **updates** (A6.2.2).*

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.

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 as a result of 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 European harmonised 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 European harmonised standards);
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 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 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 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 (pieces of) products 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 Support of an "authorised representative" established in a Member State (i.e. also in the Czech Republic) may be used in all cases.

4 Identification of legislative acts that apply to the product

4.1 There is no document or 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 **Annex C** 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** (A6.1). 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 **Detailed study** of opening sections of individual legislative texts identified in the previous step has to follow next.

4.6 The scope of application of a legislative act, i.e. definition of the range of products to which the **act applies**, is always declared in the opening sections of the text. This might serve for indication whether the legislative act applies to the product or not.

4.7 In general, exclusions of some 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.

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

4.9 The result of this analysis is the **complete list of 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 (incl. the Czech Republic) or from professional groups in these countries.*

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

4.10 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** (A3.6) (in the Czech Republic) and ask for not binding consultation. Such consultation may be provided also by Czech notified bodies (see the list in Annex D of this publication) 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 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 have to perform the risk analysis 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 (for example by fulfilling requirements of harmonised standards, if they exist) and thus safety of the product.

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 (A6.6)).

5.5 Only evidently irrelevant requirements (in respect of the product's purpose, intended use etc. – see 3.5.2a above) **may be excluded**. All other requirements have to be fulfilled. Their fulfilling has to be ensured by adequate measures applied to the product, its production, the documentation covering the product and the production as well as to the documentation 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** (A1.2) or a directly applicable EU regulation implemented by **Act 90** apply, also the relevant provisions of **Act 90** apply.

Note to 5.7, 5.8: *For identification of requirements according to 5.1, Act 22 (A4.1) and Act 90 (A4.2) have to be taken into account as well.*

5.9 A (structured) **list of all requirements** for the product's performance (possibly manufacturer's activities) identified/specified **from all legislative acts** applying to the product is the result of this step.

Note: *For identification of legislative acts applying to the product in question, the database of European harmonised standards can also be used – see the Note at the end of Chapter 6 of this publication.*

*Specific features of **construction products** are represented mainly by using different terms and their meaning (essential characteristics, performance, levels, classes of performance, threshold levels, product-type...) but the basic principle remains **analogous**. The details are laid down in the **CPR** (A2.8) + English version (A2.8.1). See also the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1), monthly **updates** (A6.2.2).*

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 European harmonised standards give a presumption of conformity only after **publishing of their references in the Official Journal of the European Union** – **OJEU** (A2.11). Until March 2019, references were published in the Commission Communication in the C series of the OJEU, any new publishing always contained the complete list of harmonised standards and replaced the previous list. Since March 2019, a new mode of publishing has been used. The references of harmonised standards are published in, and withdrawn from the OJEU (series L, no longer C) 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 (A3.5).

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

6.4 The **Czech and European** harmonised standards can be effectively searched by using the monthly updated **database of all harmonised European standards** (A6.3) + English version (A6.3.1). 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** (A6.4) + English version (A6.4.1).

Note: *The same source of information (A6.4) covers also spheres outside the 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** (A6.6). A manufacturer (in specified cases with participation of a notified subject) has to ensure and demonstrate 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.

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 hardly justifiable and therefore nearly unknown, even if they are legal and possible. (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 (see 6.5) can be used. 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 (A2.10). 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 (A6.17)) 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 (A2.10) (see 6.2) as a harmonised European standard, only the superseded version of the standard 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. During the transition period after the publication, both versions of the standard can be used for design of the product and its conformity assessment. The date when 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 (A3.5) – together with authorised dealers. For basic information – see the service **ČSN On-line** (A6.8).

6.11 The **ÚNMZ Information Portal – Regulations and Standards** (A6.1) 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). Users of the service **ČSN On-line** (A6.8) may open **fulltext versions of the European harmonised standards** directly from these updated lists.
Monthly updates of the portal can be followed in the **archive of updates** (A6.1.1).

*Specific features of **construction products** – the current process of development of harmonised standards for the CPR is not adequate, nearly one quarter of harmonised standards having been replaced by new ones (see the pink tinged standards in the database of standards harmonised to the CPR (A6.9) + English version (A6.9.1)) without their not being published in the OJEU as harmonised. Nowadays, the review of the CPR (a European Commission project) is under way aim of which is to ensure compliance of technical specifications with the CPR as well as to assess possible need for revision of the CPR (see A6.9.4).*

*Other specific features of **construction products** – European Assessment Documents (EAD) **(A6.9.2)** are also used as technical specifications under the CPR. Until March 2019, they were published in the C series of the OJEU, any new publishing always contained the complete list of EAD's and replaced the previous list. Since March 2019, only new and withdrawn EAD's have been published in the OJEU (series L) by means of Commission implementing decisions related to the CPR (A2.8). New **database of European assessment documents** (A6.9.2) + English version (A6.9.4) + product areas according ti Annex IV of the CPR (A6.9.5).*

7 Identification of conformity assessment procedures before placing of the 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. There exist 8 basic modules, with their modifications together 16, named A to H1 (see Annex C). 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 (A2.7). 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);

- 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, application for its services, results, information, communication;
- production, quality system;
- controls of products, production, quality system, surveillance, approval of a batch;
- declaration of conformity and conformity marking;
- keeping of documents and documentation;
- authorized representative.

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.

7.3 The **crucial procedure** – independently of Decision 768 (A2.7), 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.

*In the area of **construction products**, the above mentioned modules are not used. Systems of "**assessment and verification of constancy of performance**" (AVCP) are used for construction products, i.e. systems 1, 1+, 2+, 3, and 4. The CPR also regulates the so called "simplified procedures for micro-enterprises" and "other simplified procedures". **Government Order No. 163/2002 Coll.** (A4.7) also provides for specific conformity assessment procedures.*

New act on construction products is being prepared in the Czech Republic which should (as effective of 1 January 2022) repeal Government Order No. 163/2002 and introduce the CPR systems into the national legislation (A6.9.3).
*The details are laid down in the **CPR (A2.8)**, see also the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1), monthly **updates** (A6.2.2).*

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 (for example tests, inspections, certification etc.) then this procedure/module (including outputs) will be carried out only once but with differences in details laid down in the individual acts.

7.5 The principal output from this analysis has to be also the identification of **mandatory involvement** of a notified body (NB) in the conformity assessment process. Scope of such mandatory involvement of an NB 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 an NB 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.
Both types of services are provided on a **commercial basis**.

7.7 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.*

8 Choosing the appropriate notified body

8.1 For realisation of mandatory services 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) (A2.12), 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) (A2.11.1);
- the list of **AAAO** members (A3.2.1) and their websites, see also Annex D of this publication;
- the list of notified bodies in the Czech Republic on ÚNMZ websites (A3.1.3).

*For **construction products**, using the **database of harmonised standards** for CPR (A6.9) + English version (A6.9.1)) is recommended for choice of a notified body (see definition 020). Each entry of a harmonised standard is accompanied by names name of bodies (including Czech bodies) notified for it (linked directly to the **NANDO** database).*

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** (A2.11).

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 notified bodies, ÚNMZ among others:
- assesses competence of applicants for authorization and notification according to Act 22, Act 90, and Act 206;
- notifies the assessed bodies to the European Commission and other EU Member States;
- publishes authorizations and notifications in the Journal of the Office (A2.14);
- 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) + English version (A4.1.1) and **Act 90** (A4.2) + English version (A4.2.1).

For an outline of all ÚNMZ activities, see **full version in Czech** (A3.1.2), **basic English version** (A3.1.1, **basic Russian version** (A3.1.2).

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** (A2.6). Accreditation in the Czech Republic is performed in accordance with Regulation 765 by the only Czech accreditation body – **Czech Accreditation Institute (CAI)** (A3.4) + English version (A3.4.1). Rules for accreditation as well as the scope of accreditation of individual organizations can be seen on the CAI website.
Please note that as of 16 July 2021 Regulation 765 will be amended by Regulation 1020 (A2.16). The amendment will concern both the title and some provisions – see Article 39 of Regulation 1020.

8.4 Outputs of conformity assessment carried out by notified bodies established in the Czech Republic are **valid** within the whole EU/EEA.

8.5 The expert competence and offer of services of notified bodies, members of the AAAO (A3.2) and others, is in general broader than their activity in the position of notified bodies. It is demonstrated among others by means of accreditation but in particular for activities **outside the frame 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 product 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)** in Annex D of this publication and detailed information on their respective websites.

9 Realisation of conformity assessment procedures

9.1 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.

9.2 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 (A2.7) use various types of modules (see 7.1 and Annex C of this publication).

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 is **identification of all risks** with potential 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 and vice versa on the probability; and
c) 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;
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, 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 have to be subjected to validation 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.

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 "prolongation" 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. This may be for example planned 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: *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 12100). The above mentioned principles are the same and applicable also in other situations and are generally described for example in ČSN ISO 31 000.*

Note 2*:*
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 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 (in force from 16 July 2021) (A2.16 and definition 012.1).
According to Regulation 1020 (A2.16 and definition 012.1), products are (in relation to risks) specified as follows:

a) *"**product presenting a risk**" – a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable EU harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;*
b) *"**product presenting a serious risk**" – a product presenting a risk, for which, based on a risk assessment and taking into account the normal and foreseeable use of the product, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate;*

Note 3*:*
According to Regulation 1020 (A2.16), the corrective action required to be taken by the economic operator may include, among others:

a) *bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable EU harmonisation legislation, or by ensuring that the product no longer presents a risk;*
b) *preventing the product from being made available on the market;*
c) *withdrawing or recalling the product immediately and alerting the public to the risk presented;*
d) *destroying the product or otherwise rendering it inoperable;*
e) *affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;*
f) *setting prior conditions for making the product concerned available on the market;*
g) *alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.*

Corrective actions referred to in points e), f), and g) may only be required in cases where the product is liable to present a risk only in certain conditions or only to certain end users.

Market surveillance authorities ensure that products presenting a serious risk are withdrawn or recalled, where there is no other effective means available to eliminate the serious risk, or that their being made available on the market is prohibited. Market surveillance authorities notify the European Commission of this action immediately, in accordance with Article 20 of Regulation 1020 (Rapid Information Exchange System).

A decision whether or not a product presents a serious risk is based on an appropriate risk assessment that takes account of the nature of the hazard and the likelihood of its occurrence.

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 an NB 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 according to globally united rules, published on the website of **CAI** (A3.4) + English version (A3.4.1).

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.

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) 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 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 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.

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 for the work of the subcontractor lies with the subcontracting notified body.

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
a) may be laid down in a technical standard (non-harmonised) or in other technical specifications;
b) or drawn up according to the manufacturer's consideration in compliance with the general technical and scientific knowledge stated in technical and scientific literature.

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 (A2.12) + English version (A2.12.1).

9.6 Conformity assessment in mass production

9.6.1 The manufacture has the general obligation to ensure that **every piece** of the product he is placing on the market meets all relevant requirements of legislative acts. The frame for conformity assessment of products from repeated/mass production is based on the modular structure (see also Annex C of this publication):
- 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).

9.6.2 In the first two consequent cases not only the product itself (its specimen as the representative of the product type/model) is assessed but also the production (possibly also pre-production stages) 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 by concrete government orders differently. Act 90 (A4.2), Section 6, subsection 2 does not lay down any general period of time leaving it to the government orders.

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 old legislative acts), the form and content of which 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 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 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 (common) EU declaration of conformity** even if more legislative acts apply to the product. 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, content etc,

9.8.5 Some legislative acts require **each item of the product** to be accompanied by the "EU/EC declaration of conformity".

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.

*For **construction products**, as of 1 July 2013, "EU/EC declaration of conformity" is no longer being drawn up but a document called "**Declaration of performance**". The details are laid down in the **CPR** (A2.8), see also the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1), monthly updates (A6.2.2).*

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 the relevant EU harmonisation legislative acts requiring 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 internal market.

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 changes in the 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** (A2.6) + English version (A2.6.1) (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 (A2.4), conditions for affixing the CE marking are also described in Decision 768 (A2.7) and in the relevant legislative acts and 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, with support of the decision of the notified body concerned.

10.5 The CE marking is to be affixed to the product itself, its label or packaging.
Electronic CE marking **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 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 party 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, use also for the conformity assessment of the product. Unfortunately, it must be said that in this part the 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 their Czech transpositions) though they cannot be regarded legislative acts from the area of placing of specified products to the market. Provisions contained in these acts may differ from the rules described in this publication (for example the **ecodesign** of products) (A6.12).

*For all **construction products** to which a harmonised European/Czech standard applies or for which a "European technical approval" (**ETA**) has been issued the CE marking is the **only** marking. It confirms the construction product's conformity with the performance declared in the "Declaration of performance" in relation to essential characteristics according to the standard or ETA.*

*Affixing of the CE marking is **mandatory** for all construction products for which the manufacturer draws up the "Declaration of performance". The details are laid down in the **CPR (A2.8)**, see also the **ÚNMZ Information Portal – Construction Products** (A6.2) + English version (A6.2.1).*

*The European Commission issued an information publication concerning the CE marking of construction products: **CE Marking of Construction Products Step by Step** (A2.13) + English version A2.13.1).*

11 Accompanying documentation

11.1 This documentation accompanies the product from its production 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 conformity assessment of the product 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 (in responsibility of the manufacturer/supplier);
i) expected replacements of worn-out parts (in responsibility of the manufacturer/supplier);
j) diagnostics including HW and SW (in responsibility of the manufacturer/supplier);
k) system and distribution of spare parts (in responsibility of the manufacturer/supplier);
l) expected troubleshooting (in responsibility of the manufacturer/supplier);
m) etc. – the list need not be exhaustible and is not limited.

11.4 The **second** possible or rather **necessary** group of documents is intended for users of the products (both legal and private persons). It is connected primarily with use of products and activities of users. It is derived from requirements of the legislative acts and connected technical specifications, with substantial and reasonable sectoral 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 the product and protection against sanctions resulting from non-fulfilling the requirements of legislative acts (i.e. incorrect placing of the products on the market, their improper distribution 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 (10 years) 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;
e) required qualification of the user, (possibly compulsory) training provided by the manufacturer/supplier;
f) assembling, installation and putting into operation (if in responsibility of the owner/operator/user);
g) proper using, handling, adjustment, maintenance (in responsibility of the owner/operator/user);
h) safety principles for using, adjusting, maintenance, repairs, incl.:
    ha) residual risks and measures for their elimination (see also 9.3.4b);
    hb) negligible risks (see also 9.3.4c);
    hc) meaning of safety inscriptions, pictures and pictograms on the product/packaging;
    hd) use of personal protection equipment, parameters for purchase;
    he) and others;
i) monitoring of operation and wear and tear, mandatory preventive replacement of parts etc. (see also 9.3.7);
j) mandatory use of contracted manufacturer/supplier's service;
k) troubles and troubleshooting (in responsibility of the user/operator/owner);
l) available repair shops and services, spare parts distribution;
m) 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 and Note 2 in 11.5));
n) disposal of the product;
o) etc. – the list need not be exhaustible and is not limited, some items overlap.

11.7 Material intended for propagation, presentation, training etc. will have rather different character. Even these materials must correspond to other documentation and reflect the facts.

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 lay down, for concrete situations and concrete products, details as well as further procedures and differences from the general principles described here.

12.3 Due to its restricted extent, this publication cannot cover all specificities. The principles described in the text have been chosen in order to cover, as much as possible, the situations common for various products and manufacturers.

12.4 A much more detailed document is for example the **"Blue Guide on the implementation of EU product rules 2016"** (A2.12) + English version (A2.12.1).
***Note**: Update of this publication is being prepared.*

12.5 In the Czech Republic, the entrepreneurs may use the **ÚNMZ Information Portal – Regulations and Standards"** (A6.1).

*The ÚNMZ Information Portal contains also the section on **construction products**. Detailed information from this sector is also on the relevant part of the website of the Coordinating institute in the field of construction products authorized by the ÚNMZ (A6.11).*

12.6 In relation with Regulation 1020 (A2.16) which is due to enter into force on 16 July 2021 and whose aim 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 prepare themselves for these provisions in advance.

12.7 A useful source of information for entrepreneurs and public is also the information portal of ITC Zlín, a. s. "**Zákony a normy**" (in Czech) (A6.13), on laws and standards which 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. Its full version is subject to payment but a lot of information is accessible for free.

12.8 Other recommended **sources of information in the EU**:
- **EUR – Lex** (A1.3) – access to the EU law in all EU official languages and the following websites;
- **Portal Your Europe** (A6.18) – practical guide to doing business in Europe – for orientation of entrepreneurs and citizens in the European legislation and various national legislations of the EU Member States;

as well as the following important websites:
- **EU/European Union** (A1.1) – general information/Newsroom;
- **European Commission** (A1.2) – European Commission – Internal Market, Industry, Entrepreneurship and SMEs (GROWTH)**;**
- **EUROLAB** (A1.4) – European Federation of National Associations of Measurement, Testing and Laboratories **;**
- **EA – European Accreditation** (A1.5);
- **CEOC** (A1.6) – International Confederation of Inspection and Certification Organisations.

Annex A

Links to information sources

Note: *The following links are numbered identically as in the previous text. However, the list contains also other links useful chiefly for placing a product on the internal market of the EEA by way of its placing on the market in the Czech Republic. Responsibility for the content of documents linked lies with their owners.*

No	Name	Address
1	**Organisations and institutions in the EU**	
1.1	European Union – Newsroom (in English)	*http://europa.eu/newsroom/home_en*
1.2	European Commission – Internal Market, Industry, Entrepreneurship and SMEs	*http://ec.europa.eu/growth/*
1.3	EUR – Lex – website providing access to the EU legislation in all EU official languages	*http://eur-lex.europa.eu/*
1.4	EUROLAB aisbl (in English)	*http://www.eurolab.org/*
1.5	EA – European Accreditation (in English)	*http://www.european-accreditation.org/*
1.6	CEOC – International Confederation of Inspection and Certification Organisations (in English)	*http://www.ceoc.com/*
1.9	PCP – Product Contact Points – contact points for free movement of products (in Engllish)	*http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/*
1.10	Internal Market – market of the EU/EEA countries (in all EU official languages)	*http://ec.europa.eu/priorities/internal-market_en*
2	**EU legislative acts and documents** *(incl. information systems/databases containing them)*	
2.1	Directive 2001/95/EC on general product safety – in Czech	*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:CS:PDF*
2.1.1	Ditto in English	*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:EN:PDF*
2.3	Guide to the implementation of directives based on the new approach and the global approach – in Czech (see 2.12)	*https://op.europa.eu/en/publication-detail/-/publication/4f6721ee-8008-4fd7-acf7-9d03448d49e5*
2.3.1	Ditto in more EU official languages (see 2.12.1)	*https://publications.europa.eu/en/publication-detail/-/publication/4f6721ee-8008-4fd7-acf7-9d03448d49e5*
2.4	New Legislative Framework – in Czech	*https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/pravni-predpisy/novy-legislativni-ramec/*
2.4.1	Ditto in all EU official languages	*http://ec.europa.eu/growth/single-market/goods/new-legislative-framework_cs*
2.5	Regulation 764 Regulation (EC) No 764/2008 – in Czech (since 19 April 2020 repealed and replaced by Regulation 515 – see 2.14)	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:32008R0764&from=EN*
2.5.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0764*
2.6	Regulation 765 Regulation (EC) No 765/2008 – in Czech (as of 16 July 2021 will be amended by Regulation 1020 – see 2.16)	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:02008R0765-20080813&qid=1539264180668&from=CS*
2.6.1	Ditto in English	*https://eur-lex.europa.eu/legal-*

		content/EN/TXT/PDF/?uri=CELEX:32008R0765&from=EN
2.7	Decision 768 Decision No 768/2008/EC – in Czech	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:02008D0768-20080709&qid=1539264285707&from=CS*
2.7.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008D0768*
2.8	CPR – Regulation (EU) No 305/2011 – Construction Products Regulation – CPR – consolidated version - in Czech (as of 16 July 2021 will be amended by Regulation 1020 – see 2.16)	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:02011R0305-20140616&qid=1539264760921&from=CS*
2.8.1	Ditto in English	*http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0305-20140616&qid=1415779782801&from=CS*
2.9	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 (consolidated version) – in Czech	*http://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:02013L0029-20130629&qid=1480947654602&from=CS*
2.9.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0029*
2.10	OJEU – Official Journal of the EU – quick search in all EU official languages (incl. Czech)	*https://eur-lex.europa.eu/oj/2017/02/direct-access.html?locale=cs s*
2.11	NANDO – New Approach Notified and Designated Organisations – information system of notified bodies	*http://ec.europa.eu/growth/tools-databases/nando/index.cfm*
2.11.1	Ditto – list of Czech notified bodies in NANDO	*http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=203*
2.12	Blue Guide 2016 – in Czech	*http://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=OJ:JOC_2016_272_R_0001&from=CS*
2.12.1	Ditto in English	*http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_272_R_0001&from=CS*
2.13	EU brochure "CE marking of construction products step by step" – in Czech	*http://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/CE-marking_CS_150622%20final.pdf*
2.13.1	Ditto in English	*https://ec.europa.eu/docsroom/documents/12308/attachments/1/translations/en/renditions/native*
2.14	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 – in Czech	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:32019R0515&from=CS*
2.14.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0515*
2.15	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 – in Czech	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:31985L0374&from=SK*
2.15.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/SK/ALL/?uri=CELEX:31985L0374*
2.16	Regulation 1020 Regulation (EU) 2019/1020 of the European	*https://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=CELEX:32019R1020&fro*

	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 – in Czech It shall apply from 16 July 2021	*m+*
2.16.1	Ditto in all EU official languages	*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020*
3	**Organisations and institutions in the Czech Republic** *(incl. their information systems/databases)*	
3.1	ÚNMZ – Czech Office for Standards, Metrology and Testing	*https://www.unmz.cz/*
3.1.1	Ditto in English (basic information)	*https://www.unmz.cz/en/home/*
3.1.2	free	
3.1.3	ÚNMZ – list of notified bodies in the Czech Republic	*https://www.unmz.cz/statni-zkusebnictvi/autorizovane-osoby-oznamene-subjekty/seznam-ao-os-a-uno/* *https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=203*
3.1.4	Ditto in English	
3.1.5	ÚNMZ – scope of authorisation or notification of notified bodies in the Czech Republic	
3.1.6	ÚNMZ – principles of authorisation and notification in the Czech Republic	*https://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/Pokyn%20P1_01.01.2020.pdf*
3.1.7	ÚNMZ – Journal of the Office	*https://www.unmz.cz/urad/vestnik-unmz*
3.1.8	ÚNMZ – Program for Development of Testing	*https://www.unmz.cz/statni-zkusebnictvi/program-rozvoje-zkusebnictvi/*
3.2	AAAO – Association of Accredited and Authorised Organisations	*http://www.aaao.cz/*
3.2.1	AAAO – list of AAAO members	*http://www.aaao.cz/clenove/*
3.3	ProCoP – Product Contact Point at Ministry of Industry and Trade of the Czech Republic	*https://www.mpo.cz/cz/zahranicni-obchod/podnikani-v-EU/sluzby-pro-podnikatele-na-vnitrnim-trhu-eu/procop/default.htm*
3.3.1	Contact point for (harmonised and non-harmonised) CE marked construction products according to Regulation (EU) No 305/2011 on construction products	*http://www.mpo.cz/cz/stavebnictvi-a-suroviny/kontaktni-misto-pro-stavebni-vyrobky/kontaktni-misto-pro-stavebni-vyrobky-s-oznacenim-ce-podle-narizeni-c--305-2011-eu--o-stavebnich-vyrobcich--147227/*
3.4	CAI – Czech Accreditation Institute	*https://www.cai.cz/*
3.4.1	Ditto in English	*https://www.cai.cz/?page_id=12864&lang=en*
3.4.2	CAI – database of accredited subjects	*https://www.cai.cz/?page_id=4499*
3.4.3	Ditto in English	*https://www.cai.cz/?page_id=12902&lang=en*
3.5	Czech Standardization Agency	*http://www.agentura-cas.cz/o-nas*
3.5.1	Ditto in English	*http://www.agentura-cas.cz/?language=en*
3.6	Authorities responsible for implementation of EU legislation into the Czech legislation – central authorities of the Czech Republic	*https://isap.vlada.cz/dul/dirtaiii.nsf/gestor?OpenView*
4	**Czech laws**	
4.1	Act 22 – Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended (version effective from 1 September 2017)	*https://www.zakonyprolidi.cz/cs/1997-22/zneni-20170901*
4.1.1	Ditto in English – free	
4.2	Act 90 – Act No. 90/2016 Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended	*https://www.zakonyprolidi.cz/cs/2016-90/zneni-20180612*

	(version effective from 12 June 2018)	
4.3	Act 206 – Act No. 206/2015 Coll., on pyrotechnics	*https://www.zakonyprolidi.cz/cs/2015-206*
4.4	Act 102 – Act No. 102/2001 Coll., on general safety of products	*https://www.zakonyprolidi.cz/cs/2001-102*
4.5	Act 263 – Act No. 263/2016 Coll., the Atomic Act	*https://www.zakonyprolidi.cz/cs/2016-263*
4.5.1	Decrees for implementation of the Atomic Act (Decrees No. 358, 359, 360, 361, 362/2016 Coll.)	*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	*https://www.zakonyprolidi.cz/cs/1997-173*
4.7	Government Order 163 – Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products, as amended	*https://www.zakonyprolidi.cz/cs/2002-163*
4.8	Government Order 208 – Government Order No. 208/2015 Coll., on technical requirements for pyrotechnical articles and their making available on the market (version of 4 September 2016)	*https://www.zakonyprolidi.cz/cs/2015-208*
4.9	Draft of Czech market surveillance act	*https://apps.odok.cz/veklep-detail?pid=ALBSBS5ASH3V*
4.10	Act 64 – Act No. 64/1986 Coll., the Czech Trade Inspection Authority Act	*https://www.zakonyprolidi.cz/cs/1986-64*
5	**Product sectors**	
5.1	Sectors of specified products	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti*
5.2	Product sectors under Act 22	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2*
5.2.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2*
5.3	Product sectors under Act 90	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133*
5.3.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133*
5.6	**Product sectors** *For each sector:* - *EU harmonisation legislative act – in Czech and in English, incl. preambles;* - *Czech legislative act in Czech;* - *Slovak legislative act in Slovak;* - *relevant notified bodies in the EU;* - *link to valid references of harmonised standards in the OJEU* *All regardless of relation to Act 22/Act 90 in the Czech Republic.*	
5.6.1	Low voltage equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/89*
5.6.2	Simple pressure vessels (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/105*
5.6.3	Marine equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/184*
5.6.4	Measuring instruments (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/104*
5.6.5	Personal protection equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/210*
5.6.6	Radio equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/193*
5.6.7	Recreational craft and personal watercraft (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/135*
5.6.8	Appliances burning gaseous fuels (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/213*

5.6.9	Pressure equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/195*
5.6.9.1	Pressure equipment (transitional period)	*https://www.nlfnorm.cz/ehn/kategorie/110*
5.6.10	Non-automatic weighing instruments (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/103*
5.6.11	Explosives for civil uses (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/97*
5.6.12	Electromagnetic compatibility (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/90*
5.6.13	Lifts (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/109*
5.6.14	Equipment and protective systems intended for use in potentially explosive atmospheres (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/134*
5.6.15	Cableway installations (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/211*
5.6.16	Aerosol dispensers	*https://www.nlfnorm.cz/ehn/kategorie/187*
5.6.17	Ecodesign requirements for household refrigerating appliances	*https://www.nlfnorm.cz/ehn/kategorie/113*
5.6.18	Noise emissions (NOI)	*https://www.nlfnorm.cz/ehn/kategorie/186*
5.6.19	Emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery	*https://www.nlfnorm.cz/ehn/kategorie/188*
5.6.20	European rail system (high-speed and conventional)	*https://www.nlfnorm.cz/ehn/kategorie/112*
5.6.21	Toys	*https://www.nlfnorm.cz/ehn/kategorie/85*
5.6.22	Restriction of the use of certain hazardous substances in electrical and electronic equipment	*https://www.nlfnorm.cz/ehn/kategorie/93*
5.6.23.1	Personal protective equipment (placed on the market by 20 April 2019)	*https://www.nlfnorm.cz/ehn/kategorie/86*
5.6.23.2	Personal protective equipment (NLF)	*https://www.nlfnorm.cz/ehn/kategorie/210*
5.6.24	Transportable pressure equipment	*https://www.nlfnorm.cz/ehn/kategorie/185*
5.6.25	Appliances burning gaseous fuels (transitional period)	*https://www.nlfnorm.cz/ehn/kategorie/107*
5.6.26	Construction products CE marked (reduced version; for detailed version, see 6.9)	*https://www.nlfnorm.cz/ehn/kategorie/84*
5.6.27	Machinery	*https://www.nlfnorm.cz/ehn/kategorie/106*
5.6.28	Efficiency requirements for new hot-water boilers (BED)	*https://www.nlfnorm.cz/ehn/kategorie/183*
5.6.29	Medical devices	*https://www.nlfnorm.cz/ehn/kategorie/95*
5.6.30	Active implantable medical devices	*https://www.nlfnorm.cz/ehn/kategorie/94*
5.6.31	In vitro diagnostic medical devices	*https://www.nlfnorm.cz/ehn/kategorie/96*
5.6.32	Pyrotechnic articles	*https://www.nlfnorm.cz/ehn/kategorie/100*
5.6.33	Selected construction products not CE marked	*http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_5_vybran.htm* *or:* *https://www.zakonyprolidi.cz/cs/2002-163*
5.6.34	Selected products for conformity assessment (in the Czech Republic)	*https://www.unmz.cz/urad/vybrane-vyrobky* *or:* *https://www.zakonyprolidi.cz/cs/1997-173*
6	**Internet portals and databases**	
6.1	ÚNMZ Information Portal – Regulations and Standards	*https://www.unmz.cz/urad/informacni-portal-unmz*
6.1.1	Ditto – outline of monthly updates	*https://www.nlfnorm.cz/normy/480/shrnuti-zmen-provedenych-v-aktualnim-prehledu-norem-481*
6.2	ÚNMZ Information Portal – Construction Products	*https://www.unmz.cz/urad/informacni-portal-unmz-specializovany-na-pravni-a-technicke-dokumenty-v-oblasti-uvadeni-stavebnich-vyrobku-na-jednotny-evropsky-trh-c233*
6.2.1	Ditto in English	*https://www.unmz.cz/urad/information-portal-*

		construction-products
6.2.2	Ditto – outline of monthly updates	*https://www.nlfnorm.cz/en/normy/72/shrnuti-zmen-provedenych-v-aktualnim-prehledu-norem*
6.3	Database of harmonised standards	*https://www.nlfnorm.cz/normy/475/databaze-harmonizovanych-norem-477*
6.3.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/475/databaze-harmonizovanych-norem-477*
6.4	Harmonised standards grouped by sectors and areas	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti*
6.4.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti*
6.5	**Harmonisation of standards outside the specified products**	
6.5.1	Ditto – Horizontal legislative acts – New Legislative Framework and management systems	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=3*
6.5.2	Ditto – General safety (mandate standards)	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=4*
6.5.3	Ditto – Other selected sectors	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=5*
6.5.4	Ditto – Services	*https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=105*
6.6	Harmonisation legislative acts WITHOUT harmonised European standards	*http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/sektor_dalsi%20_22.htm*
6.7	Specified Czech standards	*https://www.nlfnorm.cz/informacni-portal/150/aktualizovane-prehledy-urcenych-csn*
6.8	ČSN On-line	*http://www.agentura-cas.cz/csn-online*
6.8.1	Ditto – Sale of foreign standards and withdrawn ČSN a ON	*http://www.agentura-cas.cz/prodej-zahranicnich-norem*
6.9	Database of harmonised European standards to the CPR	*https://www.nlfnorm.cz/normy/70/prehled-harmonizovanych-norem-k-cpr*
6.9.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/70/prehled-harmonizovanych-norem-k-cpr*
6.9.2	European Assessment Documents (EAD) to the CPR	*https://www.nlfnorm.cz/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr-*
6.9.2.1	Ditto in English	*https://www.nlfnorm.cz/en/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr-*
6.9.2.2	Groups of harmonised standards and EAD's according to Annex IV of the CPR	*https://www.nlfnorm.cz/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku-podle-prilohy-iv-k-cpr*
6.9.2.3	Ditto in English	*https://www.nlfnorm.cz/en/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku-podle-prilohy-iv-k-cpr*
6.9.3	Forthcoming legislation for construction products	*https://www.unmz.cz/informace-ohledne-stavebnich-vyrobku-ktere-prechazeji-z-neharmonizovane-sfery-do-harmonizovane/*
6.9.4	Revision of the CPR	*http://www.sgpstandard.cz/editor/files/stav_vyr/1_3_cpr.htm?skipRedirect=1#_Toc505849541*
6.10	Specified standards to Government Order 163 (4.7)	*http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/tech_poz/cr/pp_cr/vybr_stav/un_163_2002/un_163_2002.htm*
6.11	Information of the Coordinating institute in the field of construction products authorized by the ÚNMZ	*https://koordinacesv.tzus.cz/koordinacni-pracoviste*
6.11.1	Technical guides to Government Order 163 (4.7)	*https://koordinacesv.tzus.cz/technicke-navody*
6.12	ECO – regulations and standards for	*http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/e*

	ecodesign and energetic labels of appliances	*ko.htm*
6.13	Information portal ITC Zlín "Zákony a normy" ("Laws and Standards")	*https://www.nlfnorm.cz/informacni-portal*
6.14	Portal "Zákony pro lidi" ("Laws for people")	*https://www.zakonyprolidi.cz/*
6.15	Portal of public administration	*https://www.mvcr.cz/clanek/portal-verejne-spravy.aspx*
6.16	Information system for implementation of EU legislation	*https://isap.vlada.cz/homepage.nsf/verejnost*
6.17	Commission decisions based on objections against publication of harmonised European standards in the OJEU	*https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/formal-objections_en*
6.18	Portal Your Europe	*https://europa.eu/youreurope/citizens/index_cs.htm*

Annex B

Sectors of specified products according to EU and Czech legislative acts

The sectors are linked in Annex A to the updated sections of the ÚNMZ Information portal (A6.1).
The following up-to-date items can be opened in each sector:

- harmonised EU legislative acts in English and in Czech (official translations including preambles);
- corresponding Czech legislative acts in Czech;
- corresponding legislative acts of the Slovak Republic;
- lists of NBs for the relevant legislative act from the NANDO database;
- the last publication of harmonised standards in the OJEU;
- lists of all harmonised (specified) standards for each sector.

***Note 1**: With regard to entry into force and possibility of using of some legislative acts according to the NLF (A2.4) concurrently with the former legislative acts being replaced, these sectors may be, for some time, listed in the ÚNMZ Information Portal (A6.1) under both Act 90 (A4.2) and Act 22 (A4.1).*

Users which have the paid service **ČSN on-line** (A6.8) purchased from ČAS (A3.5) installed on their PC can open the fulltext versions of harmonised (specified) Czech standards ČSN.

The following differentiation between areas under **Act 22** (A4.1) and **Act 90** (A4.2) is valid on 1 July 2020. The sectors under Act 22 are supposed to migrate under Act 90 in future.

Active links to information sources are in Annex A under the numbers in brackets (Ax.y.z).

a) Sectors under Act 90 (New Legislative Framework)

- (A5.6.1) Low voltage equipment (NLF);
- (A5.6.2) Simple pressure vessels (NLF);
- (A5.6.3) Marine equipment (NLF);
- (A5.6.4) Measuring instruments (NLF);
- (A5.6.5) Personal protective equipment (NLF) *);
- (A5.6.6) Radio equipment (NLF);
- (A5.6.7) Recreational craft and personal watercraft (NLF);
- (A5.6.8) Appliances burning gaseous fuels (GAR) (NLF) *);
- (A5.6.9) Pressure equipment (NLF);
- (A5.6.10) Non-automatic weighing instruments (NLF);
- (A5.6.11) Explosives for civil uses (NLF);
- (A5.6.12) Electromagnetic compatibility (NLF);
- (A5.6.13) Lifts (NLF);
- (A5.6.14) Equipment and protective systems intended for use in potentially explosive atmospheres (NLF);
- (A5.6.15) Cableway installations (NLF) *);

b) Sectors under Act 22 (harmonised area)

- (A5.6.16) Aerosol dispensers;
- (A5.6.17) Ecodesign requirements for household refrigerating appliances *);
- (A5.6.18) Noise emissions (NOI);
- (A5.6.19) Emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery *);
- (A5.6.20) European rail system (high-speed and conventional) **);
- (A5.6.21) Toys;
- (A5.6.22) Restriction of the use of certain hazardous substances in electrical and electronic;
- (A5.6.23) Personal protective equipment;
- (A5.6.24) Transportable pressure equipment;
- (A5.6.26) Construction products CE marked *);
- (A5.6.27) Machinery;
- (A5.6.28) Efficiency requirements for new hot-water boilers;
- (A5.6.29) Medical devices ***);
- (A5.6.30) Active implantable medical devices ***);

- (A5.6.31) In vitro diagnostic medical devices ***)

c) Sectors under Act No. 206/2015 Coll.

- **(**A5.6.32) Pyrotechnic articles;

d) Sectors under Act 22 (non-harmonised area)

- (A5.6.33) Selected construction products;
- (A5.6.34) Selected construction products for conformity assessment;
- (A4.5) Atomic Act;
    - (A4.5.1) Decrees for implementation of the Atomic Act;

*) Sectors for which a directly applicable legislative act (regulation) has been issued.

**) Partial (legislative) transposition of Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union has been realised by amendment of the Act on rail systems. The technical transposition will be realised by the next amendment. Act 90 will apply only to notification of conformity assessment bodies.

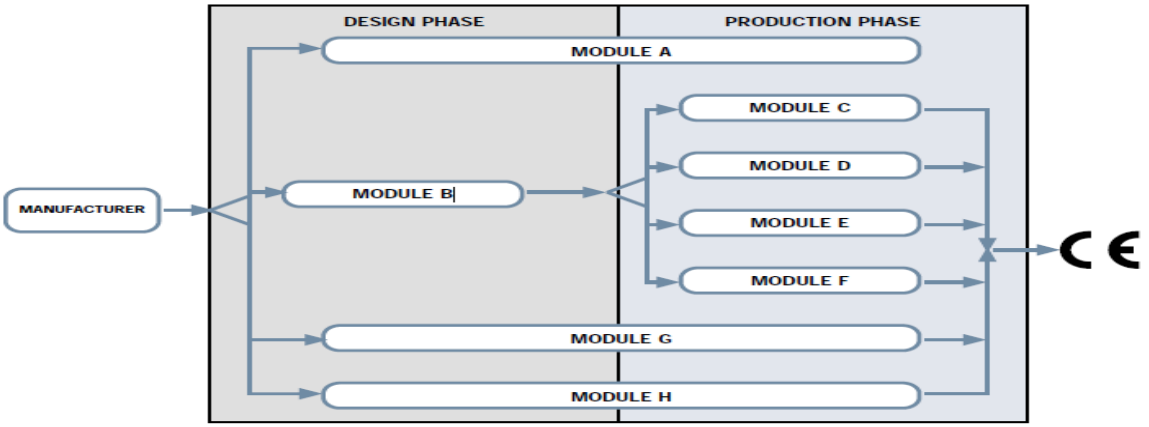
***) Adaptation of Act 90 to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices is under preparation. Government orders No. 54/2015 Coll. and No. 55/2015 Coll. will be repealed.

***Note 2**: Sectors under Act 22 (A4.1) concerning the European harmonisation legislation for specified products will gradually migrate under Act 90 (A4.2) depending on issuing of European directives (NLF) and their transposition into the Czech legislation by new government orders and also depending on issuing of new directly applicable EU regulations.*
The actual situation can be followed on the ÚNMZ Information Portal in sections (A5.1):
- *sectors to **Act 22** (A4.1);*
- *sectors to **Act 90** (A4.2).*

Annex C

Outline of conformity assessment modules (according to European harmonisation acts)

MODULES – in general current state + future
- according to the New Legislative Framework
- concretely according to **Decision 768** (A2.7), Annex II
The New Legislative Framework HAS NOT CHANGED the structure of the modules.



Conformity assessment activities:

M – manufacturer
AIB – accredited in-house body
NB – notified body

Module A:	**Internal production control**	
A1:	Internal production control plus supervised product testing	**(M)**
A2:	Internal production control plus supervised product checks at random intervals	**(AIB, NB)**
Module B:	**EC-type examination**	**(NB)**
Module C:	**Conformity to type based on internal production control**	**(M)**
C1:	Conformity to type based on internal production control plus supervised product testing	**(AIB, NB)**
C2:	Conformity to type based on internal production control plus supervised product checks at random intervals	**(AIB, NB)**
Module D:	**Conformity to type based on quality assurance of the production process**	**(NB)**
D1:	Quality assurance of the production process	**(NB)**
Module E:	**Conformity to type based on product quality assurance**	**(NB)**
E1:	Quality assurance of final product inspection and testing	**(NB)**
Module F:	**Conformity to type based on product verification**	**(NB)**
F1:	Conformity based on product verification	**(NB)**
Module G:	**Conformity based on unit verification**	**(NB)**
Module H:	**Conformity based on full quality assurance**	**(NB)**
H1:	Conformity based on full quality assurance plus design examination	**(NB)**

List of AAAO members (A3.2.1) – updated: 1 September 2020

AAAO is an association of accredited and authorised organisations or notified bodies in the Czech Republic. Its members act as independent third party organisations with the common aim being to ensure assessment of conformity of products, services, personnel, processes and systems. Responsibility for the concrete data lies with the relevant AAAO member.
The list is being updated in the public sector of www.aaao.cz.

01
Elektrotechnický zkušební ústav, s.p.
(*Electrotechnical Testing Institute, s.p.)*
(*Электротехнический испытательный институт)*
Pod Lisem 129, 171 02 Praha 8 – Troja, IČ 00001481
www.ezu.cz

02
Strojírenský zkušební ústav, s.p.
(*Engineering Testing Institute)*
(*Инженерно-испытательный институт*)
Hudcova 424/ 56b, 621 00 Brno, IČ 00001490
www.szutest.cz

03
Technický a zkušební ústav stavební Praha, s.p.
(*Technical and Test Institute for Construction Prague, SOE)*
(*Государственное предприятие «Технический и испытательный строительный институт Прага»)*
Prosecká 811/76a, 190 00 Praha 9 – Prosek, IČ 00015679
www.tzus.cz

04
STAVCERT, zájmové sdružení právnických osob
(STAVCERT)
(STAVCERT - объединение юридических лиц)
Jablonského 640/2, 170 00 Praha 7, IČ 67364209
www.stavcert.cz

05
Silniční vývoj – ZDZ spol. s r.o.
(Road Research Institute – Testing Laboratory of Traffic Signs)
(*Дорожный исследовательский институт - Тестирование дорожных знаков)*
Jílkova 76, 615 00 Brno, IČ 64507181
www.silvyvoj.cz

06
Mendelova univerzita v Brně
(*Mendel University Brno)*
(Университет Менделя в Брно)
Zemědělská 1, 613 00 Brno, IČ 62156489
www.mendelu.cz
Doručovací adresa: Zkušebna STV Zlín, Louky 304, 763 02 Zlín
www.zstv.cz

07
Fyzikálně technický zkušební ústav, s.p.
(*Physical - Technical Testing Institute)*
(*Физико-технический испытательный институт)*
Pikartská 1337/7, 716 07 Ostrava – Radvanice, IČ 00577880
www.ftzu.cz

08
TÜV SÜD Czech s.r.o.
(*TÜV SÜD Czech s.r.o.)*
(TÜV SÜD Czech s.r.o.)
Novodvorská 994, 142 21 Praha 4, IČ 63987121

www.tuv-sud.cz

09
VVUÚ, a.s.
(VVUU)
(VVUU)
Pikartská 1337/7, 716 07 Ostrava – Radvanice, IČ45193380
www.vvuu.cz

10
PAVUS, a.s.
(*The Fire Research Institute)*
(Институт противопожарной безопасности)
Prosecká 412/74, 190 00 Praha 9, IČ 60193174
www.pavus.cz

11
Zkušebna kamene a kameniva, s.r.o.
(Stone and Aggregates Test Centre, LTD.)
(Испытательная лаборатория камня и агрегатов)
Husova 2274, 508 01 Hořice, IČ 64828042
www.zkk.cz

12
Textilní zkušební ústav, s.p.
(*Textile Testing Institute)*
(Текстильный испытательный институт)
Václavská 6, 658 41 Brno, IČ 00013251
www.tzu.cz

13
Ministerstvo vnitra - generální ředitelství Hasičského záchranného sboru ČR - Technický ústav požární ochrany
(*The Ministry of Interior - General Directorate of the Fire Rescue Service of the Czech Republic - Fire Technical Institute)*
(Министерство внутренних дел – Технический институт противопожарной защиты)
Písková 42, 143 01 Praha 4 – Modřany; IČ 00007064
Fakturační adresa: Ministerstvo vnitra, Nad Štolou 936/3, 17034 Praha 7
zastoupené: MV-GŘ HZS ČR, Technický ústav požární ochrany, Písková 42, 143 01 Praha 4 – Modřany
www.hzscr.cz

14
Institut pro testování a certifikaci, a.s.
(*Institute for Testing and Certification, a.s.)*
(*Институт тестирования и сертификации)*
třída Tomáše Bati 299, Louky, 763 02 Zlín, IČ 47910381
www.itczlin.cz

15
IKATES, s.r.o.
(IKATES)
(IKATES)
Tolstého 186, 415 03 Teplice 3, IČ 25032836
www.ikates.cz

16
Výzkumný ústav pozemních staveb - Certifikační společnost, s.r.o.
(*Building Research Institute – Certification Company)*
(*Строительный исследовательский институт - Сертификационная компания)*
Pražská 16, 102 21 Praha 10 - Hostivař , IČ 25052063
www.vups.cz

17
Výzkumný ústav bezpečnosti práce, v.v.i.
(*Occupational Safety Research Institute)*
(*Исследовательский институт охраны труда)*
Jeruzalémská 1283/9, 110 00 Praha 1, IČ 00025950
www.vubp.cz

18
QUALIFORM a.s.

(QUALIFORM)
(QUALIFORM)
Mlaty 672/8, 642 00 Brno
Doručovací adresa: Mlaty 8, 642 00 Brno-Bosonohy, IČ 49450263
www.qualiform.cz

19
Výzkumný ústav pro hnědé uhlí, a.s.
(*Brown Coal Research Institute)*
(*Исследовательский институт бурого угля)*
Budovatelů 2830/3, 434 01 Most, IČ 44569181
www.vuhu.cz

20
Český metrologický institut
(Czech Metrology Institute)
(Чешский метрологический институт)
Okružní 31, 638 00 Brno, IČ 00177016
www.cmi.cz

21
TECHNICKÉ LABORATOŘE OPAVA, akciová společnost
(Technical Laboratories Opava)
(Технические лаборатории Опава)
Těšínská 2962/79B, 746 41 Opava, IČ 25667521
www.tlo.cz

22
Vojenský technický ústav, s.p.
(Military Technical Institute)
(Военный технический институт)
Mladoboleslavská 944, 197 06 Praha 9 – Kbely, IČ 24272523
Osoba pověřená výkonem činností - doručovací adresa AO:
Vojenský technický ústav, s.p. odštěpný závod VTÚPV
V.Nejedlého 691, 682 01 Vyškov
www.vtusp.cz

23
SILMOS-Q s.r.o.
(SILMOS-Q)
(SILMOS-Q)
Křižíkova 70, 612 00 Brno, IČ 26918927
www.silmos-q.cz

24
Státní zkušebna strojů, a.s.
(*Government Testing Laboratory of Machines)*
(Государственная лаборатория машин , акционерное общество)
Třanovského 622/11, 163 04 Praha 6 – Řepy, IČ 27146235
www.statnizkusebna.cz

25
Technická inspekce České republiky
(Technical Inspection of Czech republik)
(Техническая инспекция Чешской республики)
U Balabenky 1908/6, P.O.BOX č. 107, 180 00 Praha 8, IČ 00638919
www.ticr.cz

26
Výzkumný Ústav Železniční, a.s.
(Railway Research Institute)
(Железнодорожный исследовательский институт)
Novodvorská 1698, 142 01 Praha 4 – Braník, IČ 27257258
www.cdvuz.cz

27
Vysoká škola báňská-Technická univerzita, Výzkumné energetické centrum
(*Technical University of Ostrava)*
(Горный университет – Технический университет, Испытательный энергетический центр)

17. listopadu 15/2172, 708 33 Ostrava – Poruba, IČ 61989100
http://vec.vsb.cz

28
TREZOR TEST, s.r.o
(*TREZOR TEST)*
(*TREZOR TEST)*
Na Vršku 67, 250 67 Klecany, IČ 47544147
www.trezortest.cz

29
TÜV AUSTRIA CZECH spol. s r. o.
(TÜV AUSTRIA CZECH spol. s r. o.)
(TÜV AUSTRIA CZECH spol. s r. o.)
Zelený pruh 1560/99, Praha 4 – Braník, 140 02, IČ: 26427753
www.itiv.cz

30
Laboratoř M O R A V A s.r.o.
(Labor MORAVA)
(Лаборатория МОРАВИЯ)
Oderská 456, 742 13 Studénka, IČ: 25399951
www.laborator-morava.cz

31
Výzkumný a vývojový ústav dřevařský, Praha, s. p.
(Timber research and Development institute, Prague)
(Исследовательский институт дерева, Прага)
Na Florenci 7-9, 111 71 Praha 1, IČ: 00014125
www.vvud.cz

32
TÜV NORD Czech, s.r.o.
(TÜV NORD Czech, s.r.o.)
(TÜV NORD Czech, s.r.o.)
Českomoravská 2420/15, 190 93, Praha 9, IČ: 45242330
www.tuev-nord.cz

33
DOM – ZO 13, s.r.o
(DOM – ZO 13, s.r.o)
(DOM – ZO 13, s.r.o)
Litomyšlská 1637, 560 02 Česká Třebová, IČ: 25261908
www.domzo13.cz

34
BUREAU VERITAS CERTIFICATION CZ, s.r.o.
(BUREAU VERITAS CERTIFICATION CZ, ltd.)
(BUREAU VERITAS CERTIFICATION CZ, s.o.)
Olbrachtova 1, 140 00 Praha 4 – Krč, IČ: 26165007
www.bureauveritas.cz

35
HEATEST, s.r.o.
(HEATEST, ltd.)
(HEATEST, s.o.)
276 01Býkev čp. 84, IČ:27390951
http://www.heatest.cz

36
Technický dozorčí spolek Brno, z. s.
(Technical Safety Corporation Brno)
(ОБЩЕСТВО ТЕХНИЧЕСКОГО НАДЗОРА, БРНО)
U vlečky 29/5, Komárov, 617 00 Brno, IČ:64439356
http://www.tdssms.cz/

Appendix

Identification of changes of EU and Czech legislative acts

"Version 2020" reflects changes of the legislation which occurred between 31 July 2018 and 31 July 2020 according to the following table.

Item	Basic legislative acts regulating placing of products on the market	Main changes as against 2018 *Current state of legislation – see the "ÚNMZ Information Portal – Regulations and Standards"* *https://www.unmz.cz/urad/informacni-portal-unmz*
1	NLF – Regulation 764	Regulation 764 - since 19 April 2020 repealed and replaced by Regulation 515 – see Item 2
2	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. The aim of this regulation is to strengthen functioning of the internal market by application of the mutual recognition principle and removal of unjustified trade obstacles. The regulation lays down rules and procedures concerning application of the mutual recognition principle by Member States in relation to goods which has been placed on the market in another Member State in compliance with the latter's legislative acts. It also provides for establishment and operation of product contact points in Member States as well as cooperation and exchange of information in relation to the mutual recognition principle. It is one of two new regulations of the so called "The Goods Package: Reinforcing trust in the single market". *(in this publication taken into account)* The regulation has been applied since 19 April 2020, before that date Regulation 764 was applied, see Item 1.
3	NLF – Regulation 765 as amended	Regulation 765 will be amended on 16 July 2021 – partly repealed and replaced with Regulation 1020 – see Item 4
4	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. The aim of this regulation is to improve functioning of the internal market by strengthening the market surveillance of products to which the EU harmonisation legislative acts apply in order to ensure that only the products compliant with the regulations and fulfilling requirements for high level of protection of justified concern are made available on the market. The regulation lays down rules and procedures for economic operators concerning products with some EU harmonisation legislative acts and creates the framework of cooperation with economic operators as well as for control on products entering the EU market. It is the second of two new regulations of the so called "The Goods Package: Reinforcing trust in the single market". *(in this publication taken into account according to amendments in*

		Regulation 765; as far as the market surveillance area is concerned, this publication only refers to relevant obligations of economic operators) The entire regulation will be applied from 16 July 2021. For implementation of this directly application piece of legislation, a draft act on market surveillance is under preparation in the Czech Republic – see Item 15.
5	NLF – Decision 768 as amended	No changes
6	Another harmonisation in the EU	After the harmonisation legislative acts mentioned in Items 2 and 4, no changes in the horizontally applicable regulations are in sight. Only some directives or regulations (EU) concerning concrete product sectors (e.g. safety of toys) are amended or completed.
7	Act 22 – Act No. 22/1997 Coll. as amended by Act No. 91/2016 Coll., Act No. 183/2017 Coll., and Act No. 265/2017 Coll.	Since ca February 2019 a draft act amending Act 22 and Act 90 has been undergoing the legislative process. Its part concerning Act 90 represents adaptation to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices. The part concerning Act 22 reflects the "sponsored access" to standards as well as changes in the accreditation process. *The legislative procedure has not been finished yet (by 31 July 2020).* *(No substantial correction of this publication is presumed.)*
8	Act 90 – Act No. 90/2016 Coll., as amended by Act No. 183/2017 Coll. and Act No. 265/2017 Coll.	Draft Act – see Item 7.
9	Government orders implementing Act 22	Update on harmonisation legislative acts and relevant harmonised 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. Updates on national Czech government orders not harmonised with the EU. (Current state – Annex B of this publication.) *(All these changes reflected in the links in Annex A, if they have any impact on the publication's text.)*
10	Government orders implementing Act 90	See Item 9.

11	Directly applicable EU harmonisation legislative acts for products (regulations)	As of 16 July 2021, according to Article 40 of Regulation 1020 (A2.16) the first subparagraph of Article 56 of Regulation (EU) No 305/2011 (CPR – construction products) will be replaced by the following: *"1.Where the market surveillance authorities of one Member State have sufficient reason to believe that a construction product covered by a harmonised standard or for which a European Technical Assessment has been issued does not achieve the declared performance and presents a risk for the fulfilment of the basic requirements for construction works covered by this Regulation, they shall carry out an evaluation in relation to the product concerned covering the respective requirements laid down by this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities."* A project of the European Commission – CPR Technical Acquis – is under way aimed at ensuring compliance of technical specifications with the CPR. Simultaneously, the CPR is being analysed and needs for possible revision of the CPR identified, see A6.9.4. *The legislative procedure has not been finished yet (by 31 July 2020).* In June 2019, the legislative procedure for draft act on medical devices started. By means of this act, the Czech legislation will be adapted to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (together with adaptation to Act 22); Government Orders No. 54/2015 Coll. and No. 55/2015 Coll. will be repealed. The act on medical devices will be amended simultaneously – it will apply to in vitro diagnostic medical devices. *The legislative procedure has not finished yet (31 July 2020).* *(Harmonisation and relevant Czech legislative acts in the medical devices area bring in some practical principles and procedures of conformity assessment and placing on the market which slightly differ from those in other sectors of specified products. This fact will not be reflected in the text of this publication for the transitional period.)*
12	Preparation of a new act on construction products	A separate **act on construction products and their use in construction works** is being prepared, with presumed entry into force in the year 2022. Its main principles are: unification of rules for the harmonised and non harmonised areas, requirements on control of products deliveries on the construction site and their correct use in the construction works. Government Order No. 163/2002 Coll. should be repealed and two new legislative acts should be issued for implementation of the new act. *The legislative procedure has not been finished yet (by 31 July 2020).* *http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_1_leg_prip.htm*
13	Preparation of an amendment of Act No. 206/2015 Coll., on pyrotechnic products ...	The amendment reacts a.o. to correction of Directive 2013/29/EU. It also regulates the competence of persons handling of pyrotechnic products, extends its application on natural persons. *The legislative procedure has not been finished yet (by 31 July 2020).*
14	Preparation of an amendment of Act No. 266/1994 Coll., on rail systems	Partial (legislative) transposition of Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union has been realised by amendment of the Act No. 367/2019 Coll. amending Act No. 266/1994 Coll., on rail systems. The technical transposition will be realised by the next amendment of the act

	etc.	on rail systems. Act 90 will apply only to notification of conformity assessment bodies. *The legislative procedure has not been finished yet (by 31 July 2020).*
15	Preparation of an act on market surveillance and compliance of products with legislation	A separate **act on market surveillance act and on compliance of products with legislation...** (A4.9) is being prepared aiming at implementation of Regulation 1020 (see Item 4 above). The draft act lays down rules for institutional organisation of market surveillance in the Czech Republic, completes the competences of market surveillance authorities in the Czech Republic for the legislative acts listed in Annex I of Regulation 1020. It lays down measures applied in case of breach of requirements of legislative acts or endangering of public interest. It also appoints the central liaison office for communication with the European Commission and other Member States, The draft act lays down some competences of market surveillance authorities concerning the enforcement of obligations laid down in the EU harmonisation legislative acts not embodied in the Czech national legislation (especially in the act on controls). The draft act will amend those Czech legislative acts containing provisions concerning the market surveillance, such as Act 22 (A4.1), Act 90 (A4.2), Act 102 (A4.4), Act 64 (A4.10) etc. *The legislative procedure has not been finished yet (by 31 July 2020).*
End of Appendix		

Accompanying data:

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Contractor: Association of Accredited and Authorised Organisations (AAAO)
Author: Josef Šenk
Based on the publications:
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and
"**Uvádění stanovených výrobků na trh** (version 2019)",

issued by AAAO with support of ÚNMZ in 2018 and 2019.

End of publication incl. annexes.
Prague, 10 November 2020.