



How to verify that medical devices and personal protective equipment can be lawfully placed on the EU market and thus purchased and used - also in the COVID-19 context

Introduction and scope of this document

The purpose of this guidance document is to provide basic indications to allow those interested parties who are unfamiliar with the regulated sectors of medical devices and personal protective equipment to identify whether a product is lawfully placed on the EU market and can continue to be made available, thus purchased and used.

Such clarification has proven especially necessary in the context of the COVID-19 pandemic¹. The related extraordinary circumstances have rapidly increased the need and demand for certain devices and equipment: this has resulted in the involvement of economic operators and other interested parties not previously in the supply and verification chain of these products. In addition, recent experience indicates the need to be attentive to misleading or falsified documents as well as to counterfeit products.

Question 1: What is the applicable regulatory framework for medical devices and personal protective equipment in the EU?²

Medical devices within the EU are currently regulated by the following Directives:

- [Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices](#)³ (hereafter referred to as AIMDD)
- [Council Directive 93/42/EEC of 14 June 1993 concerning medical devices](#)⁴ (hereafter referred to as MDD)
- [Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices](#)⁵ (hereafter referred to as IVDD)

Medical devices can also already be placed on the EU market if they comply with the following new Regulations which entered into force in May 2017:

¹ Commission's coronavirus response: <https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response>.

² See also Question 9 for more detailed information.

³ OJ L 189, 20.7.1990, p. 17.

⁴ OJ L 169, 12.7.1993, p. 1.

⁵ OJ L 331, 7.12.1998, p. 1.

[Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC](#)⁶ (hereafter referred to as MDR, fully applicable as from 26 May 2021)

- [Regulation \(EU\) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU](#)⁷ (hereafter referred to as IVDR, fully applicable as from 26 May 2022)

The temporal scope and the conditions of applicability of the relevant legal requirements to devices, from the AIMDD, the MDD and the IVDD (hereafter referred to as Directives) to the MDR and the IVDR (hereafter referred to as new Regulations on medical devices), are governed by specific transitional provisions⁸.

On the other hand, personal protective equipment within the EU is currently regulated by [Regulation \(EU\) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC](#)⁹ (hereafter referred to as PPER).

Question 2: How can a product be lawfully placed on the EU market?

In order to lawfully place on the EU market medical devices under the scope of the Directives or the new Regulations, as well as personal protective equipment under the scope of the PPER, these products must be CE-marked¹⁰ with the EC or EU declaration of conformity signed and issued by the manufacturer.

In the EC or EU declaration of conformity, manufacturers must declare that their products comply with the applicable EU legislative act(s) and requirements. There are however no obligations in the EU legal framework to separately draw up declarations of compliance with national legislation, as well as with national, European or international standards.

The Directives and the new Regulations on medical devices, and the PPER, in line with the main pieces of the EU legislation concerning the internal market for goods, lay down essential safety and performance requirements and health and safety requirements, respectively, but do not prescribe any specific mandatory technical solutions for the manufacturing and design of the products. Therefore, the manufacturer can choose

⁶ OJ L 117, 5.5.2017, p. 1.

⁷ OJ L 117, 5.5.2017, p. 176.

⁸ See Article 120 MDR and Article 110 IVDR.

⁹ OJ L 81, 31.3.2016, p. 51.

¹⁰

The CE marking must be affixed according to the specific provisions laid down in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 (OJ L 218, 13.8.2008, p. 30) as well as in the applicable EU legislation.

which technical solution(s) to use to comply with these legal requirements. Manufacturers can use those offered in harmonised European standards or in other standards or technical specifications, or can come up with their own technical solution(s).

The use of harmonised European standards is a voluntary means to comply with the legal requirements. These standards, developed by the relevant European standardisation organisations¹¹, contain specific technical solutions that can be used to comply with the legal requirements. When the reference of a harmonised European standard is cited in the *Official Journal of the European Union* (OJEU), the use of such standard confers on the product a presumption of conformity with the legal requirements it aims to cover (as listed in the relevant Annex Z). In practice, where a manufacturer chooses to follow a harmonised European standard to which the reference is cited in the OJEU, the product is presumed to be in conformity with the applicable legal requirements covered by such standard. On the contrary, where a manufacturer chooses not to follow a harmonised European standard, it must demonstrate that the alternative technical solution applied is adequate to ensure compliance of the product with the applicable legal requirements.

The manufacturer must also prepare and maintain the relevant technical documentation for the product, in support to the compliance claimed in the EC or EU declaration of conformity. Such technical documentation has to be kept and made available to national competent authorities upon their request.

For medical devices, manufacturers outside the EU must designate a single authorised representative in the EU. Information on the authorised representative must be available at least on the EC or EU declaration of conformity, on the certificate where applicable, and on the labelling of the device.

For certain medical devices¹² and personal protective equipment¹³, the manufacturer needs to involve a notified body in the prescribed conformity assessment procedure(s). Once the notified body assesses the compliance of the product with the relevant requirements of the applicable EU legislation, it will issue the appropriate certificate (as for example an EC or EU type-examination certificate, a design-examination certificate or a quality management system certificate). Such product must be CE-marked followed by the 4-digits identification number (NB xxxx) of the notified body. Conformity assessment procedures can include audits of manufacturers and/or critical suppliers/subcontractors, testing or review of technical documentation (such as test reports, manufacturer's risk assessment and/or management process, drawings and clinical data) in support of compliance of the product with the applicable legal requirements.

¹¹ The [European Committee for Standardization \(CEN\)](#) and the [European Committee for Electrotechnical Standardization \(CENELEC\)](#) for the medical devices and personal protective equipment sectors.

¹² Medium and high-risk devices such as medical face masks supplied in sterile condition, respiratory patient ventilators, *in vitro* diagnostic devices listed in Annex II to the IVDD and diagnostic self-tests.

¹³ Risk categories II and III such as respiratory protection face masks.

Question 3: Can other documents be valid to lawfully place a product on the EU market?

Only documents which are explicitly referred to in the applicable EU legislation (namely the EC or EU declaration of conformity and, where needed, certificates issued according to the relevant conformity assessment procedures) may be drawn up and used for the purpose of lawfully placing a product on the EU market. Therefore, any other document is not valid for such a purpose. In practice there are several examples of documents which have no legal status according to the applicable EU legislation, for instance the so-called “*certificate of compliance*”, “*attestation of compliance*”, “*certificate of conformity*”, “*certificate of notification*”, “*certificate of registration*”, “*documentation review* or similar, which do not comply with the requirements of an EC or EU declaration of conformity issued by the manufacturer or a certificate issued by a notified body.

Those “other documents” with no legal status according to the applicable EU legislation are issued by different kinds of entities, for instance non-notified conformity/certification bodies but also bodies notified under other EU legislative acts, or testing houses or laboratories, or even authorised representatives, etc. Even if such documents may include some elements of a declaration of conformity or a certificate, they are usually voluntary statements that manufacturers request from third parties but do not provide any legal basis to place products on the EU market. These statements may address different issues such as compliance with legislation or standards, appropriateness of the technical documentation and so on, but do not constitute “declarations of conformity” (because valid declarations of conformity can only be issued by manufacturers) nor “certificates” (because valid certificates can only be issued by notified bodies designated for the specific legislative act) within the meaning of the applicable EU legislation.

These voluntary statements may be included in the technical documentation as supporting documents to provide evidence of compliance with certain applicable requirements. However, they can never replace the EC or EU declaration of conformity issued by the manufacturer, or the certificate(s) issued by notified bodies, as prescribed by the applicable EU legislation.

Question 4: Which are the main characteristics of a valid declaration of conformity?

A valid EC or EU declaration of conformity must be drafted and signed by the manufacturer, and include as a minimum¹⁴:

- the identification and description of the product;

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The model structure of the EC declaration of conformity is set out in Annex III to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 (OJ L 218, 13.8.2008, p. 82). In addition, indications on the contents of the EU declaration of conformity can be found in “The ‘Blue Guide’ on the implementation of EU products rules” (see Question 9).

- the EU legislative act(s) to which conformity is claimed;
- the name and address of the manufacturer, and/or of the authorised representative, where applicable;
- a statement that the declaration is issued under the sole responsibility of the manufacturer;
- the conformity assessment procedure(s) applied;
- references to the relevant harmonised European standard(s) or common specification(s) used, where applicable;
- the name and the 4-digits identification number (NB xxxx) of the notified body and reference to the certificate(s) issued, where applicable;
- date of issue of the declaration, identification and signature of the manufacturer.

The minimum contents of the EU declaration of conformity according to the new Regulations on medical devices are laid down in the respective Annexes IV.

The minimum contents of the EU declaration of conformity according to the PPER are laid down in Annex IX.

If a product falls under the scope of two or more EU legislative acts providing for the CE marking, a single EU declaration of conformity must be drafted and signed by the manufacturer, declaring conformity with the applicable two or more pieces of legislation. This is the case, for instance, of "double-purpose" medical protective equipment, such as some types of face masks or gloves, providing protection to both users and patients: they fall under the scope of both the MDD and the PPER, therefore their EU declaration of conformity will refer to both pieces of legislation.

Question 5: Which are the main characteristics of a valid certificate?

There are two types of certificates that can be issued by a notified body under the applicable EU legislation, in view of placing medical devices or personal protective equipment on the EU market: product certificates and quality management system certificates. The first certifies that the product complies with the relevant requirements (after the notified body has reviewed the relevant technical documentation and/or has performed the relevant tests). The latter certifies the quality management system of the manufacturer for a defined product range (either in its entirety or in aspects limited to production or product quality assurance).

A valid certificate under the applicable EU legislation (as for example an EC or EU type-examination certificate, a design-examination certificate or a quality management system certificate) is issued by a notified body after the successful completion of the conformity assessment procedure applicable to the product. Notified bodies are designated by the relevant national authorities to perform specific conformity assessment procedure(s) and thus to issue the related certificate(s), for specific types of products or quality management systems under different EU legislative acts. Only those notified bodies listed in the Commission's NANDO information system

<https://ec.europa.eu/growth/tools-databases/nando/> are entitled to issue valid certificates, within their scope and competences:

- List of notified bodies for the AIMDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8
- List of notified bodies for the MDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
- List of notified bodies for the IVDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20
- List of notified bodies for the MDR: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- List of notified bodies for the IVDR: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35
- List of notified bodies for the PPER: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

A conformity assessment body must be notified under each specific EU legislative act in order to be able to perform determined conformity assessment procedure(s) for specific types of products under the said legislative act, as indicated in the notification with its scope and the competences of the notified body. Thus, even if a body is notified under one or more EU legislative act(s) and has thus been granted a 4-digits identification number (NB xxxx) in NANDO, such notified body is not automatically allowed to perform conformity assessment procedures under other EU legislative act(s) or for different scope and competences. A separate notification is therefore necessary, even if the notified body will keep the same identification number under each EU legislative act.

The NANDO information system can be consulted searching by "Country", "Legislation" or "Body". For each notified body and notifying/designating authority, information and contact details are included: this can be used to submit requests for specific information on the status and competences of notified bodies, as well as on their activities. In addition, several notified bodies listed in NANDO for medical devices and personal protective equipment have dedicated websites where the most relevant information on their certificates can be consulted.

A manufacturer can choose any of the notified body listed in NANDO if notified for the specific EU legislative act(s), irrespective of where the notified body is located.

Every certificate issued by a notified body prior to placing medical devices or personal protective equipment on the EU market must specify the conformity assessment procedure applied, and may include references to the test reports if applicable and other relevant technical documents, as well as to the harmonised European standards used if it is the case. The name and the 4-digits identification number (NB xxxx) of the notified body must be clearly indicated on the certificate.

Guidance on content of certificates issued by notified bodies for medical devices in

accordance with the Directives can be found in the document NBOG BPG 2010-3¹⁵, detailing information to be reported depending on the relevant conformity assessment procedure performed.

The minimum contents of certificates according to the new Regulations on medical devices are laid down in their respective Annexes XII.

The minimum contents of an EU type-examination certificate according to the PPER are laid down in its Annex V.

Question 6: When is the intervention of a notified body required?

For medical devices, the involvement of a notified body is required for the conformity assessment procedures applicable to class III, IIa and IIb devices, as in the case of respiratory patient ventilators, as well as for class I devices supplied in sterile condition or with measuring functions. For other class I devices, as in the case of medical face masks (often referred to as type I, II or IIR masks^{16 17 18}), gloves and overalls when supplied in non-sterile condition, the intervention of a notified body is not required, and manufacturers are entitled to carry out the applicable conformity assessment procedure under their sole responsibility ("self-assessment").

For *in vitro* diagnostic medical devices, under the IVDD, notified body intervention is required for devices intended for self-testing, i.e. devices intended by the manufacturer to be used by lay persons in a home environment⁷. It is also required for devices listed in Annex II of the IVDD. Under the IVDR, notified bodies are involved in conformity assessment of class B, C and D devices, as well as class A sterile devices.

For products under the scope of the PPER, a notified body is required for the conformity assessment procedures applicable to risk categories II and III equipment. In particular, respiratory protection face masks used in the COVID-19 context (often referred to as FFP2 or FFP3 masks) are products falling in category III and as such a notified body must be systematically involved in the conformity assessment procedures prior to placing these products on the EU market.

Question 7: Can a test report in accordance with a standard allow for the placing on the EU market of a product?

A test report issued after carrying out testing on a product in accordance with a standard is not sufficient by itself for lawfully placing the product on the EU market. This is the case also for harmonised European standards providing presumption of conformity to certain requirements. Test reports, as well as documentation of the

<http://www.doks.nbog.eu/Doks/NBOG BPG 2010 3.pdf>.

¹⁶ As defined in the harmonised European standard [EN 14683:2019+AC:2019](#).

¹⁷ Article 1 (2)(d) IVDD.

¹⁸ As defined in the harmonised European standard [EN 149:2001+A1:2009](#).

manufacturer's risk assessment and/or management process, drawings, clinical data etc., are to be included in the technical documentation prepared by the manufacturer.

Where applicable, these elements must be submitted to a notified body, which will review them and conduct additional tests if necessary. Notified bodies cannot issue any certificate based on test reports only: the relevant conformity assessment procedure(s) have to be performed. Once the relevant conformity assessment procedure has been successfully completed, in order to place products on the EU market according to the applicable legislation, such products must be CE-marked (followed by the 4-digits identification number (NB xxxx) of the notified body when applicable) with the EC or EU declaration of conformity signed and issued by the manufacturer.

This is the case, for instance, of test reports for medical face masks in accordance with the harmonised European standard [EN 14683:2019+AC:2019](#), or test reports for respiratory protection face masks in accordance with the harmonised European standard [EN 149:2001+A1:2009](#) (in this case, documentation should be submitted by the manufacturer to the notified body which will perform the tests and the applicable conformity assessment procedures). Reports of tests performed against the relevant standards could be considered as one, but not the only, element based on which the manufacturer can issue the EC or EU declaration of conformity for products intended to be placed on the EU market.

Question 8: Are derogations from the legal requirements possible (for instance, products not CE-marked, or without a declaration of conformity), in particular in the context of the COVID-19 pandemic?

Under exceptional circumstances, the medical devices Directives and Regulations¹⁹ empower national competent authorities, on a duly justified request, to authorise the placing on their national markets of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of protection of health, or in the interest of public health or patient safety or health respectively ("national derogation").

On the contrary, the PPER does not envisage such possibility.

Nevertheless, in the context of the COVID-19 pandemic, the [Commission Recommendation \(EU\) 2020/403 of 13 March 2020 on conformity assessment and ¹⁹ market surveillance procedures within the context of the COVID-19 threat²⁰](#) allows for some degree of flexibility, to improve the availability of certain personal protective

¹⁹ Article 9(9) AIMDD, Article 11(13) MDD and Article 9(12) IVDD; Article 59 MDR and Article 54 IVDR. The referred Articles of the MDR and the IVDR establish also the possibility for the Commission, in exceptional cases relating to public health or patient safety or health, to extend for a limited period of time the validity of an authorisation granted by a Member State to the territory of the EU, and set the conditions under which the device may be placed on the market or put into service.

²⁰ OJ L 79I, 16.3.2020, p. 1.

equipment²¹ and medical devices²², under strict conditions and bound to healthcare workers. In this sense, national competent authorities of the EU Member States may authorise the making available on their national markets of some products, for a limited period of time and while the necessary procedures are being carried out, even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised.

Question 9: Where can more detailed information on the applicable EU regulatory framework be found?

All the relevant information on the EU legislative acts on medical devices and on personal protective equipment, with the related legal texts and requirements, guidance documents, working parties, lists of harmonised European standards and of notified bodies, contact points etc., can be found in the respective Commission's sectorial websites:

- Medical devices: <https://ec.europa.eu/growth/sectors/medical-devices>. Contact: SANTE-MED-DEV@ec.europa.eu
- Personal protective equipment: <https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment>. Contact: GROW-PPE@ec.europa.eu

Among the available guidance documents, the following ones provide further overview information about the current regulatory framework for medical devices and personal protective equipment in the EU:

- Conformity assessment procedures for protective equipment: <https://ec.europa.eu/docsroom/documents/40521>
- Guidance on medical devices, active implantable medical devices and *in vitro* diagnostic medical devices in the COVID-19 context: <https://ec.europa.eu/docsroom/documents/40607/>

For more specific information on products, their characteristics and performance, as well as the related documents, to check whether they can be validly placed on the EU market or not, it is necessary to contact the national competent authorities of the EU Member State(s) where such products are intended to be placed, as per the lists available on the Commission's sectorial websites:

- Medical devices: <https://ec.europa.eu/growth/sectors/medical-devices/contacts>
- Personal protective equipment: <https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment>

Horizontal information and guidance applicable to the various pieces of EU legislation on internal market for goods, which also include the medical devices Directives and

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In particular respiratory protection face masks, gloves, protective coveralls and eyewear protection.

22 In particular medical face masks, examination gloves and gowns.

Regulations and the personal protective equipment Regulation, are available on the following Commission's webpages:

- The 'Blue Guide' on the implementation of EU product rules:
<https://ec.europa.eu/docsroom/documents/18027/>
- CE marking: <https://ec.europa.eu/growth/single-market/ce-marking/>
- Technical documentation and EU declaration of conformity:
<https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/>
- Single market for goods: <https://ec.europa.eu/growth/single-market/goods>
- New legislative framework: <https://ec.europa.eu/growth/single-market/goods/new-legislative-framework>
- Market surveillance for products: <https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance>
- Harmonised standards: <https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards>
- NANDO (New Approach Notified and Designated Organisations) information system:
<https://ec.europa.eu/growth/tools-databases/nando/>
- Safety Gate: the rapid alert system for dangerous non-food products (RAPEX):
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

N.B. These Guidelines are intended solely for facilitating the application of the Directives and Regulations on medical devices and the Regulation on personal protective equipment. The Commission accepts no responsibility or liability whatsoever with regard to the information in this document.

The information provided in this document is:

- of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
- not necessarily comprehensive and complete;
- sometimes referring to actions of external actors over which the Commission services have no direct control and for which the Commission cannot assume responsibility;
- not of a professional nature or should not be read as legal advice.

To the extent that these Q&A's may interpret legislation, the Commission's position is without prejudice to any interpretation of this legislation that may be issued by the Court of Justice of the European Union.

如何验证医疗器械和个人防护设备是否可以合法地投放到欧盟市场上并由此进行购买和使用-同样适用于COVID-19

本文件的引言和范围

本指导文件的目的是提供基本指示，以便不熟悉医疗器械和个人防护设备的有关方面可以确定产品是否可以合法投放到欧盟市场，并且可以继续提供以便购买和使用。

事实证明，在COVID-19大流行的背景下²³，这种澄清尤为必要。

相关的特殊情况迅速增加了对某些器械和设备的需求：这导致经营者和其他以前曾未参与这些产品供应和验证链的有关方面参与进来。

另外，最近的经验表明，需要注意误导或伪造的文件以及假冒产品。

问题1：欧盟医疗设备和个人防护设备适用的监管框架是什么？²⁴

欧盟内的医疗设备目前受以下指令规范：

- 1990年6月20日理事会指令90/385 / EEC，该指令近似于成员国有源植入式医疗器械的法律²⁵（以下简称AIMDD）
- 1993年6月14日关于医疗器械的理事会指令93/42 / EEC²⁶（以下简称MDD）
- 欧洲议会和理事会于1998年10月27日发布的关于体外诊断医疗设备的指令98/79 / EC²⁷（以下简称IVDD）

如果医疗器械符合以下于2017年5月生效的新法规，则也可以投放到欧盟市场：

²³ 委员会新冠病毒应对: <https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response>.

²⁴ 参照问题9获取更多信息。

²⁵ OJ L 189, 20.7.1990, p. 17.

²⁶ OJ L 169, 12.7.1993, p. 1.

²⁷ OJ L 331, 7.12.1998, p. 1.

- 欧洲议会和理事会于2017年4月5日颁布的关于医疗器械的（EU）2017/745号法规，修订了2001/83 / EC号指令，178/2002号（EC）法规和1223/2009号（EC）法规，以及废除理事会指令90/385 / EEC和93/42 / EEC²⁸（以下称为MDR，自2021年5月26日起全面适用）
- 欧洲议会和理事会于2017年4月5日颁布的关于体外诊断医疗器械的（EU）2017/746号法规，并废除98/79 / EC号指令和2010/227 / EU号委员会决定²⁹（以下简称IVDR，从2022年5月26日开始完全适用）

从AIMDD，MDD和IVDD（以下称为指令）到MDR和IVDR（以下称为医疗器械新法规），相关法律要求对设备的适用时间范围和适用条件，受特定的过渡性规定约束³⁰。

另一方面，欧盟内部的个人防护设备目前受欧洲议会和欧盟理事会2016年3月9日关于个人防护设备的法规（EU）2016/425的管制，并废除了理事会指令89/686 / EEC³¹（以下简称“至PPER”）。

问题2：如何将产品合法地投放到欧盟市场？

为了在指令或新法规的范围内合法地将医疗器械以及在PPER范围内的个人防护设备投放到欧盟市场，这些产品必须带有CE标记

³²并带有由生产商签名和发行的符合EC或EU的合格声明。

在EC或EU合格声明中，制造商必须声明其产品符合适用的欧盟立法法令和要求。

但是，欧盟法律框架中没有义务单独起草遵守国家法律以及国家，欧洲或国际标准的声明。

关于医疗器械的指令和新法规以及PPER，与欧盟有关商品内部市场的主要法规相一致，分别规定了基本的安全和性能要求以及健康和安要求，但没有规定产品制造和设计的任何特定强制性技术解决方案。

因此，制造商可以选择使用哪种技术解决方案来满足这些法律要求。

²⁸ OJ L 117, 5.5.2017, p. 1.

²⁹ OJ L 117, 5.5.2017, p. 176.

³⁰ 参照Article 120 MDR 和 Article 110 IVDR.

³¹ OJ L 81, 31.3.2016, p. 51.

³² CE标记必须根据欧洲议会和理事会于2008年7月9日发布的法规（EC）765/2008（OJ L 218, 13.8.2008, p. 30）以及在适用的欧盟法律中。

制造商可以使用欧洲统一标准或其他标准或技术规范中提供的产品，也可以提出自己的技术解决方案。

使用欧洲协调标准是以遵守法律要求为目的的自愿行为。这些由欧洲相关标准化组织³³制定的标准包含可用于合规要求的特定技术解决方案。当欧洲联盟官方公报（OJEU）引用欧洲协调标准时，则这种标准的使用使产品假定符合其目的所涵盖的法律要求（如附件Z所列）。在实践中，如果制造商选择遵循OJEU中引用的欧洲协调标准，则假定产品符合该标准所涵盖的适用的法律要求。相反，如果制造商选择不遵循欧洲协调标准，则必须证明其采用的替代技术解决方案足以确保产品符合适用的法律要求。

制造商还必须准备并维护产品的相关技术文档，以支持EC或EU合格声明中要求的合规要求。该技术文档必须被保存，并在国家主管部门要求时出示。

对于医疗设备，欧盟以外的制造商必须在欧盟指定一个授权代表。有关获授权代表的资料必须至少在EC或EU的合格声明、适用证书和设备标签上可以获得。

对于某些医疗设备³⁴和个人防护设备

³⁵，制造商需要让指定机构参与到合格评定程序中。一旦指定机构评估产品符合适用的欧盟法规的相关要求，将签发相应的证书（例如EC或EU的类型检验证书，设计检验证书或质量管理体系证书）。此类产品必须带有CE标记和指定机构的4位标识号（NB xxxx）。合格评定程序可以包括对制造商和/或重要供应商/分包商的审核，对技术文档的检查或审查（例如测试报告，制造商的风险评估和/或管理过程，图纸和临床数据），以支持产品符合适用的法律要求。

³³ 欧洲标准化委员会(CEN)和欧洲电工标准化委员会(CENELEC)，医疗设备和个人防护设备部门。

³⁴

中高危设备，如用于无菌条件下的医用口罩、呼吸道患者呼吸机、附件二所列的体外诊断设备和自诊断检测。

³⁵ 危险等级I和III例如呼吸道防护口罩。

问题3：其他文件是否可以合法地将产品投放到欧盟市场？

只有在适用的欧盟法规中明确提到的文件(即EC或EU的合格声明，以及必要时根据相关合格评估程序签发的证书)，才可合法地将产品投放欧盟市场。因此，任何其他文件均无效。在实践中，根据适用的欧盟法规，有一些文件不具备法律效力，它们不符合制造商的EC或EU合格声明或指定机构出具的证书的要求，例如所谓的“合格证书”，“合格证明”，“合格性证明”，“通知证书”，“注册证书”，“文件审查”或类似的文件。

那些在适用的欧盟法规中没有法律效力的“其他文件”是由不同种类的实体发布的，例如，非指定合格/认证机构，也有欧盟其他法令下的指定机构，测试机构或实验室，甚至授权代表等。即使这些文件可能包含一些合格声明或证书的要素，它们通常仅为制造商要求第三方提供的自愿性声明，并不具备在欧盟市场投放产品的法律依据。这些文件可能涉及不同的内容例如是否符合法律或标准，技术文件的适用性等，但不能形成适用欧盟法律意义上的“合格声明”（因为有效的合格声明只能由制造商出具）或“证书”（因为证书只能由特定法令的指定机构出具）。

这些自愿性声明可以作为支持性文件包含在技术文档中，作为符合特定适用要求的证据。然而，它们不能取代欧盟适用法律规定的由制造商出具的EC或EU合格声明，或由指定机构出具的证书。

问题4：有效合格声明的主要特征是什么？

制造商必须起草并签署有效的欧盟委员会或欧盟合格声明，并至少包括³⁶：

³⁶ 欧盟委员会符合性声明的模板在2008年7月9日欧洲议会和理事会第768/2008 / EC号决定的附件III中有所规定（OJ L 218, 13.8.2008, 第82页）。

此外，有关欧盟符合性声明的内容的说明可以在“有关欧盟产品规则实施的《蓝色指南》中找到（请参阅问题9）。

- 产品的标识和描述；
- **要求遵守的欧盟立法法案；**
- **制造商和/或授权代理的名称和地址（如适用）；**
- 由制造商全权负责的声明；
- 适用的合格评定程序；
- 参考所使用的相关的欧洲标准或通用规范（如适用）；
- 指定机构的名称和四位数字的识别码（NB
xxxx），并在适用时引用所颁发的证书；
- 声明日期、制造商标识和签名。

根据新的《医疗器械法规》，欧盟有效合格声明的最低内容规定在相应的附件IV中。

根据PPER，欧盟有效合格声明的最低内容规定在相应的附件IX中。

如果产品属于提供CE标志的两项或多项欧盟立法法案的范围内，则制造商必须起草并签署一份欧盟有效合格声明，声明必须适用两项或多项法规。

例如，“双重用途”的医疗防护设备，某些类型的口罩或手套即为用户也为患者提供保护。它们属于MDD和PPER的范围，因此他们的欧盟有效合格声明将同时参考这两项法律。

问题5：有效证书的主要特征是什么？

考虑到将医疗设备或个人防护设备投放到欧盟市场上，根据适用的欧盟法规，指定机构可以颁发两种类型的证书：产品证书和质量管理体系证书。第一个证明产品符合相关要求（指定机构审查了相关技术文档和/或执行了相关测试之后）。后者证明了制造商针对定义产品范围的质量管理体系（无论是整体还是局限在生产或产品质量保证方面）。

在产品成功完成适用于以下方面的合格评定程序后，指定机构将根据适用的欧盟法规颁发有效证书（例如欧盟委员会或欧盟型式检验证书，设计检验证书或质量管理体系证书）。相关国家主管部门指定了公布机构，以执行特定的合格评定程序，从而根据不同的欧盟立法法规针对特定类型的产品或质量管理体系签发相关证书。只有委员会的NANDO信息系统<https://ec.europa.eu/growth/tools-databases/nando/>中列出的那些指定机构有权在其范围和权限内颁发有效证书：

-AIMDD的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8

-MDD的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13

-IVDD的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20

-MDR的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

-IVDR的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

-PPER的公告机构名单：https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

依据公告机构的范畴与能力，合格评估机构必须根据每个特定的欧盟立法法令得到通知，从而能够对该特定法令规定下的特定类型产品执行具体的合格评定程序。因此，即使一家机构是一个或多个欧盟法令中规定的公告机构并具备NANDO系统授予的4位数字识别码（NBxxxx），该机构也不会自动被允许执行其他欧盟法律法规下的合格评定程序，或在其能力范围之外执行合格评定。

在NANDO信息系统中可以依据“国家”、“法律”

或“机构”进行查询。每个公告机构和公告/指定机构的信息和联系方式已提供，可用于提交关于公告机构状态与能力及其活动的具体信息的查询请求。此外，NANDO系统中列出的一些医疗器械和个人防护设备的公告机构有专用的网站，在这些网站可以查阅与其证书最相关的信息。

如果得到特定欧盟法令的通知，制造商可以选择NANDO系统中列出的任何公告机构，无论公告机构位于何处。

每份由公告机构签发的证明，在将医疗设备或个人

防护设备引入欧盟市场之前，必须明确应用合格评定的程序，并且可能包括对测试报告

的引用（如果适用）和其他相关技术文件，以及统一的欧洲标准（如果适用）。公告机构的名称和4位数字的识别码（NB xxxx）必须在证书上明确指出。

依据指令的要求，公告机构颁发的医疗器械合格证内容指南，可以在NBOG BPG 2010-3³⁷文件中找到，详细的报告信息取决于相关的合格评定程序。

根据新的医疗设备法规，证书的最基础内容在各自的附件十二中列出。

根据欧盟个人防护用品条例，欧盟类型检验证书的最基础内容载于其附件五。

问题6：何时需要指定机构的参与？

对于医疗设备，适用于III级，IIa级和IIb级设备的合格评定程序，如呼吸患者呼吸机，以及在无菌条件下使用或具有测量功能的I级设备，要求指定机构参与。

对于其他I类设备，如非无菌状态下使用的医用口罩（通常称为I，II或IIR型口罩³⁸）、手套和防护服，则无需指定机构参与其合格评定程序，并且制造商有权自行开展适用的合格评定程序（“自我评估”）。

对于体外诊疗设备，根据体外诊断医疗器械指令（IVDD），对于旨在进行自我测试的设备，即制造商为非专业人士设计在家庭环境中使用的设备³⁹，其合格评定程序需要指定机构的参与。

体外诊断医疗器械指令附件II中列出的设备也需要指定机构的参与。

根据体外诊断医疗器械法规（IVDR），指定机构需要参与B、C和D类设备以及A类无菌设备的合格评定。

对于PPER范围内的产品，适用于II类和III类风险设备的合格评定程序需要指定机构参与。特别是，在COVID-19环境中使用的呼吸防护面罩（通常称为FFP2或FFP3面罩⁴⁰）属于III类产品，在进入欧盟市场之前，进行合格性评估时，指定机构必须全面参与。

³⁷ http://www.doks.nbog.eu/Doks/NBOG_BPG_2010_3.pdf.

³⁸ 如欧盟协调标准EN 14683:2019+AC:2019定义

³⁹ 体外诊断医疗器械指令，第1(2)(d)号条款

⁴⁰ 如欧盟协调标准EN 149:2001+A1:2009定义

问题7：是否可以根据标准的测试报告将产品投放到欧盟市场？

根据标准对产品进行测试后发布的测试报告，本身不足以准许产品合法地投放到欧盟市场。

假定符合某些要求的欧洲协调标准也是如此。

测试报告以及制造商的风险评估和/或管理过程、图纸、临床数据等文件应包含在制造商准备的技术文件中。

在适用的情况下，必须将这些文件提交给指定机构，该机构将对其进行审查并在必要时进行其他测试。指定机构不能仅根据测试报告签发任何证书：必须执行相关的合格评定程序。

成功完成相关合格评定程序后，为了根据适用的法规将产品投放到欧盟市场，此类产品必须带有CE标记（如适用，后跟认证机构的4位数字识别码NBxxxx），并带有制造商签署和发布的EC或EU合格声明。

例如，符合欧洲统一标准EN 14683：2019 +

AC：2019的医用口罩测试报告，或符合欧洲统一标准EN

149:2001+A1:2009的呼吸防护口罩测试报告就是这种情况（在这种情况下，制造商应将文件提交给进行测试和适用合格评定程序的指定机构）。将根据相关标准进行的测试报告视为一个要素，但不是唯一要素，制造商可以以此为依据向打算投放到欧盟市场的产品发布欧洲委员会或欧洲联盟合格声明。

问题8：法律要求上的部分减免是否存在可能（例如，产品无CE标志或无合格声明），尤其是在COVID-19疫情的情况下？

在特殊情况下，医疗器械指令和条例

⁴¹授权国家主管部门，在合理要求下，授权在本国市场上进行配售那些尚未执行相关合格

⁴¹ AIMDD第9（9）条，MDD第11（13）条和IVDD第9（12）条；MDR第59条和IVDR第54条。

MDR和IVDR的上述条款还为委员会提供了在与公共卫生或患者安全或健康有关的特殊情况下，在一段有限的时间内将成员国所授予的授权的有效期限延长的可能性。欧盟领土，并设置将设备投放市场或投入使用的条件。

评定程序，

但出于保护健康或公共健康或患者安全或健康的目的医疗设备（“国家减免”）。

相反，PPER并未设想这种可能性。

但是，针对COVID-19疫情，2020年3月13日委员会建议书（欧盟）2020/403

关于在COVID-19危机

⁴²的背景下进行的合格评定和9个市场监督程序的评估，在严格条件下并仅限于医护人员允许一定程度的灵活性，以提高某些个人防护设备⁴³和医疗器械

⁴⁴的可用性。从这个意义上讲，欧盟成员国的国家主管当局可以授权在一定时期内并在执行必要的程序的同时，在其本国市场上提供某些产品，即使合格评定程序包括CE标支的粘贴尚未完全完成。

问题9：在哪里可以找到适用的有关欧盟法规框架的更多详细信息？

所有相关欧盟医疗器械和个人防护设备的法律法规的信息，以及有关的法律条文和规定、指引文件、工作小组、欧洲统一标准清单、指定机构以及联络方式等，均可在欧洲委员会所属部门的网页上找到：

-医疗设备：<https://ec.europa.eu/growth/sectors/medical-devices>。联系方式：SANTE-MED-DEV@ec.europa.eu

-个人防护设备：<https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment>。联系方式：GROW-PPE@ec.europa.eu

在现有的指导文件中，以下指南提供了有关欧盟医疗设备和个人防护设备当前监管框架的进一步概述信息：

-防护设备的合格评定程序：

<https://ec.europa.eu/docsroom/documents/40521>

-关于COVID-19的医疗设备，有源植入式医疗设备和体外诊断医疗设备的指南：

<https://ec.europa.eu/docsroom/documents/40607/>

⁴² OJ L 79I, 16.3.2020, p. 1.

⁴³ 特别是呼吸防护面罩，手套，防护工作服和防护眼镜。

⁴⁴ 特别是医用口罩，检查手套和工作服。

有关产品特点和性能的详细信息以及相关文件，查询它们是否可以有效地投放到欧盟市场，根据委员会部门网站上提供的清单，有必要联系要放置此类产品的欧盟成员国的国家主管部门：

- 医疗器械：<https://ec.europa.eu/growth/sectors/medical-devices/contacts>
- 个人防护设备：<https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment>

适用于内部市场商品的相关欧盟法律的横向信息和指南（包括医疗器械指令和条例以及个人防护设备条例）可在委员会的下列网页上找到：

- 有关欧盟产品规则实施的《蓝色指南》：<https://ec.europa.eu/docsroom/documents/18027/>
- CE 标志：<https://ec.europa.eu/growth/single-market/ce-marking/>
- 技术文件和欧盟符合性声明：<https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/>
- 商品的单一市场：<https://ec.europa.eu/growth/single-market/goods>
- 新的法制框架：<https://ec.europa.eu/growth/single-market/goods/new-legislative-framework>
- 产品的市场监督：<https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance>
- 统一标准：<https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards>
- NANDO
（适用于通告和指定机构的新方法）信息系统：<https://ec.europa.eu/growth/tools-databases/nando/>
- 安全门：非食品类危险消费品快速通报系统（RAPEX）：https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

备注：这些指导意见旨在促进医疗器械指令和条例以及个人防护设备条例的实施。欧盟委员会对于本文档中的内容不承担任何责任。

本文档中提供的信息：

仅具有一般性，并不适用于任何特定个体或实体的特殊情况；

- **不具有全面性和完整性；**
- **有时是指外部行为者的行为，其不受委员会服务的直接控制，且委员会不对此负责责任；**
- **不具有专业性质，或不应被视为法律建议。**

在一定程度上，这些问答是对法律的阐释，但委员会的立场不影响欧盟法院可能对该法律做出的任何解释。
