Version 2: 10 July 2020

Conformity assessment procedures for protective equipment

This document is addressed to prospective manufacturers of protective equipment. The document will be complemented on a regular basis in order to address any additional questions or concerns expressed by the economic operators.

Q1: Which are the applicable EU legal frameworks in the case of protective equipment?

The COVID-19 is transmitted via small airborne droplets emitted by infected people when sneezing, coughing or talking. Therefore, a wide array of protective products designed to ensure protection against airborne particles or small droplets are used such as: face masks, gloves, coveralls, etc.

Most of these products are among the so-called 'harmonised products' for which there is specific EU product legislation in place. A majority of the products used in the context of the current health crisis, including FFP-type masks, are considered as Personal Protective Equipment (PPE) and hence fall under the scope of Regulation (EU) 2016/425.

Other products such as medical gloves and medical face masks are products falling within the scope of the EU legal framework on medical devices – Council Directive 93/42/EEC, to be fully replaced by Regulation (EU) 2017/745 as from 26 May 2021[1].

Each of the two legal frameworks fully harmonises the performance requirements for the products that it covers in order to ensure protection of the health and safety of users and requires the affixing of the CE marking to the products. Thus, products manufactured in accordance with these rules and bearing the CE marking can circulate freely throughout the EU internal market and Member States may not introduce additional and diverging requirements regarding the manufacturing and placement on the market of such products.

Q2: Are there mandatory EU standards, which should be followed in order to produce protective equipment?

Both the PPE Regulation and the Directive on Medical Devices lay down essential requirements on health, safety and performance of the products they cover. However, both EU legal frameworks are technologically neutral and do not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers to meet these essential requirements.

Both the PPE Regulation and the Directive on Medical Devices offer the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised standards or parts thereof. The references of these harmonised standards have been published in the *Official Journal of the European Union*. Where a manufacturer chooses to adopt such a technical solution, the product is

[1] With patient health and safety as a guiding principle, the European Parliament and the Council adopted Regulation (EU) 2020/561 of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions. This Regulation postpones the date of application for most provisions of the Regulation (EU) 2017/745 on medical devices by one year.

presumed to be in conformity with the applicable essential health, safety and performance requirements.

In the case of face masks, the harmonised standards are **EN 149:2001+A1:2009** for the FFP-type masks and **EN 14683:2019+AC:2019** for medical face masks.

Compliance with the exact specifications laid down in these standards is not mandatory since manufacturers may choose to adopt different technical solutions. However, the major advantage offered by these technical solutions is that compliance with their prescriptions gives the product the presumption of conformity to the legislation concerned and can potentially allow a swifter placement on the market.

Q3: If a manufacturer chooses to follow the EN 14683 standard on medical face masks, who should perform the tests specified therein?

The tests are prescribed in the standard and can be performed by the manufacturer himself or by a laboratory on his behalf.

These tests are not a mandatory step prior to the placement on the market, since it´s not required by the Medical Devices Directive. However, the manufacturer must ensure that the product meets the applicable essential requirements. For that purpose, the standard includes testing methods. In case of control by the market surveillance authorities, if the manufacturer claims that the product complies with the standard, a sample may be tested in accordance with the tests prescribed therein.

Q4: If a manufacturer intends to follow the EN 149 or EN 14683 standards, where can these standards be obtained?

European standards are copyright-owned by the European standardisation organisations which have developed them: for PPE and medical devices, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Normally, manufacturers must purchase the standards they need from the national members of the European standardisation organisations, i.e. the national standardisation bodies.

However, to ensure that European industry can quickly respond to the increased demand for medical and protective equipment generated by the COVID-19 outbreak, the Commission agreed with the European standardisation organisations CEN and CENELEC that a set of standards (including EN 149 and EN 14683) are exceptionally made freely and fully available by the national standardisation bodies.

Manufacturers can download the standards EN 149 and EN 14683 for free from the online catalogues of the national standardisation bodies. A full list, with links to the respective web-sites, is available at: https://standards.cen.eu/dyn/www/f?p=CENWEB:5.

Q5: Are there any other standards that can be followed in order to produce protective equipment?

Any standard or specific technical solution may be used provided that it complies with the applicable essential requirements laid down by the EU legal frameworks. While the harmonised standards (e.g. EN 149 and EN 14683 on masks above) tend to be the technical solution most widely used by the

industry in the EU, there are other specific technical solutions which ensure a comparable level of safety.

The World Health Organisation guidelines on the choice of protective equipment provide a reference in that respect.

However, in contrast to the use of harmonised standards (EN 149 and EN 14683), where a manufacturer chooses to follow one of the alternative standards referred to by the WHO, a sample of the product should be tested by a notified body (third party conformity assessment body) in the case of products falling within the scope of the PPE Regulation.

In the COVID-19 context, the Commission issued on 13 March 2020 a Recommendation to facilitate the rapid uptake of new products on the EU market. In particular, with respect to PPE face masks, the Commission urged all notified bodies to prioritise any new requests submitted by manufacturers for COVID-19 related products. The attention of the notified bodies was drawn to the fact that the WHO guidelines could present alternative adequate technical solutions.

Points 7 and 8 of the Recommendation (EU) 2020/403 encourage the adoption of derogatory measures for PPE and medical devices[2], which meet the essential health and safety requirements: point 7 authorises an anticipated placing on the market while the conformity assessment procedures are still being finalised, and point 8 enables the placement on the market even if no conformity assessment procedures have yet been initiated. Both scenarios are subject to specific and strict conditions. They require in any case the involvement and assessment by the competent market surveillance authority of the Member State in which the products will be made available.

Point 7 of the Recommendation

In the scenario under point 7 of the Recommendation, the conformity assessment procedures would have to be initiated by the manufacturer. The market surveillance authority may assess the product, including those which have been presented to the notified body for conformity assessment, where required. If the market surveillance authority ascertains that the product ensures an adequate level of health and safety in accordance with the applicable legal requirements, it may take a decision to fast-track the placing on the market of the said product.

In practice this means that, once the market surveillance authority confirms that the product is compliant, the first batch of products may already be placed on the market even if the equipment in this first batch does not bear the CE marking yet. However, as point 7 clearly stipulates, such anticipated placing on the market must be limited in time and it should not exceed the time necessary for the manufacturer to bring the products fully into compliance ("*they may authorise the making available of these products on the Union market for a limited period of time and while the necessary procedures are being carried out*"). Therefore, the timeframe of the anticipated placement on the market in the scenario under point 7 should normally be limited to only a few days. It is of paramount importance to ensure that the conformity assessment procedures are swiftly finalised.

[2] In relation to medical devices, please note that the Regulation (EU) 2017/745 constitutes the relevant legal framework for what concerns national derogations from the conformity assessment procedures. For further information, please consult the document Communication from the Commission "*Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745*", *OJ C 171, 19.5.2020, p. 1–4.*

When allowing the anticipated placing on the market of products pursuant to point 7, the market surveillance authorities should ensure that all economic operators involved have set up an efficient and functioning system for ensuring the traceability of the products. This would be particularly important in cases where the conformity assessment procedure reveals that products, which have already been placed on the market pursuant to point 7, are not fully compliant with the applicable legal requirements. In such cases, the necessary corrective actions (including the withdrawal of the products in case of serious risks to the users' health and safety) can be taken in relation to the first batches of products already placed on the market in an anticipated manner. These corrective actions will need to be taken by the economic operators under the supervision of the market surveillance authority.

In cases where the conformity assessment procedure establishes the existence of serious risks to the users' health and safety, the product may no longer be placed on the market (including pursuant to the derogatory procedures under points 7 and 8 of the Recommendation), until the necessary adaptations have been made by the manufacturer.

Point 7 of the Recommendation does not introduce any restrictions to the possible users of equipment, placed on the market under this scenario, nor does it restrict the distribution channels. Therefore, equipment which is placed on the market pursuant to the procedure laid down in point 7 of the Recommendation can be made available to a much broader range of users, including to industrial users. As a matter of fact, industrial users are best placed to use such equipment as they are expected to have received specific training, for instance as to how to use PPE in the workplace environment. Considering that the non-CE marked equipment in the first batch, which may be placed on the market in an anticipated manner, may not yet be supplied with all the necessary markings and/or instructions for use, training on the appropriate use of this PPE is an important element contributing to the users' health and safety.

Recommendation (EU) 2020/403 does not lay down specific rules as to the labelling/marking of products, which may be placed on the market in accordance with the procedure in point 7 thereof. This is justified by the multitude of possible practical scenarios, which Market Surveillance Authorities may face: differences in the progress of the conformity assessment procedure, differences of the size of the batches/amounts of non-CE marked products to be placed on the market, differences of the distribution channels/target groups, etc. All of the differences above, may justify the need for specific markings/labelling of the products. Thus, the Market Surveillance Authority, which takes the responsibility for the placement on the market of products pursuant to point 7 of the Recommendation, may also decide on the specific labelling/markings to be used in order to ensure the traceability of the products covered by this derogation, pending finalisation of the conformity assessment procedures, which will eventually result in the affixing of the CE marking.

The scenario under point 7 of Recommendation (EU) 2020/403 would be particularly applicable in cases when the products in question have been manufactured in accordance with a harmonised European standard and the manufacturer is already able to present the necessary test reports as part of the technical file presented to the notified body. Point 7 of the Recommendation is, however, not limited to such cases.

It should be noted however, that products placed on the market pursuant to the procedure under point 7 of Recommendation (EU) 2020/403 do not enjoy free movement across the EU until the

moment that the conformity assessment procedure pursuant to Regulation (EU) 2016/425 have been successfully completed.

In practice, this means that pursuant to point 7, the market surveillance authority of a given Member State may authorise the anticipated placement on the market of products only as far as the territory of this given Member State is concerned. The fact that the market surveillance authority of one Member State has authorised the anticipated placement on the market of these products on its territory does not mean that the same products may automatically be marketed on the territory of other Member States. Therefore, in order for the same product to be marketed in several Member States in accordance with the procedure under point 7 of Recommendation (EU) 2020/403, each market surveillance authority would need to assess the product and grant authorisation valid for its own territory.

This being said, once the conformity assessment procedures pursuant to Regulation (EU) 2016/425 have been successfully completed (including the affixing of the CE marking) the products previously placed on the market in an anticipated manner will be able to enjoy the free movement across the EU in accordance with Article 7 of Regulation (EU) 2016/425.

Point 8 of the Recommendation

Pursuant to point 8 of the Recommendation, in order for products to be placed on the market even if the conformity assessment procedures have not been initiated and no CE marking has been affixed upon them, the following cumulative conditions should be fulfilled:

1. the products should be manufactured in accordance with a harmonised European standard, in accordance with any of the standards referred to in the WHO guidelines[3] or any other non-EU standard or technical solution, provided that the chosen technical solution ensures an adequate level of safety in respect to the applicable legal requirements;
2. the products are part of a purchase organised by the relevant Member State authorities;
3. the products are only made available for the healthcare workers;
4. the products are only made available for the duration of the current health crisis; and
5. the products are not entering the regular distribution channels and made available to other users.

The assessment of the specific technical solution as per point 1. above is to be performed by a market surveillance authority in the course of the purchase process organised by the relevant authority of the Member State.

The reference to ”healthcare workers” in point 8 is to be interpreted in the light of recital 8 of the Recommendation as also extending to ”*first responders and other personnel involved in the efforts to contain the virus and avoid its further spread*”.

However, equipment procured by means of the derogatory procedure introduced by Point 8 should only be purchased by entities which are under the direct authority of the relevant Member State authorities, responsible for the management of the crisis. Such equipment could subsequently be

[3] https://www.who.int/emergencies/what-we-do/prevention-readiness/disease-commodity-packages/dcp-ncov.pdf?ua=1

made available only to healthcare workers and first responders, which are directly engaged in the efforts to contain the further spread of the virus.

In cases where the non-CE marked items of PPE or medical devices are not accompanied by instructions of use or care, it is important that the users of this non-CE marked equipment receive the appropriate explanations/training.

Furthermore, the relevant purchasing authority of the Member State should be able to ensure the traceability of any non-CE marked product to its final user and should be able to ensure that such equipment is not subject to resale and further commercialisation in the regular distribution channels.

Finally, please note that as far as medical devices are concerned, in order for the derogatory procedure under point 8 of the Recommendation to be applied, the national authorities of the Member State, whose authorities are authorising the placing on the market of non-CE marked medical devices should adopt national derogations pursuant to Article 59 of Regulation (EU) 2017/745.[4]

Q6: Is there any authorisation/mandatory conformity assessment or certification that needs to be performed before the products are placed on the market?

Medical face masks, examination gloves and some types of gowns (when supplied in non-sterile condition) are 'Class I medical devices'. As such, they do not require the mandatory involvement of a notified body (third party conformity assessment body) prior to being placed on the market. The manufacturer must declare that the product complies with the applicable requirements. This regime is essentially one of self-assessment. Self-assessment is the conformity assessment procedure by which the manufacturers test the products on their own (possibly with the support of an external laboratory), draw up the technical documentation and declare their conformity with the applicable essential requirements laid down in the EU legislation. If such devices are supplied in a sterile condition, it is required to involve a notified body responsible to carry out the conformity assessment procedure.

Conversely, face masks and other equipment used in the COVID-19 context that are covered by the PPE Regulation are considered as 'PPE of Category III'. Therefore, a notified body must be involved in all cases during the conformity assessment procedure. Samples of the product need to be presented by the manufacturer to such a body for assessment prior to placing on the market. However, under the PPE Regulation, once the initial samples are tested, there is no obligation to subject every single item coming off the production line to the same tests. Instead, there are supervised product checks at random intervals or other similar production control procedures, which are put in place.

Q7: Should the CE marking be affixed in all circumstances?

Under the usual procedures for placing products on the market, the CE marking is the final step, marking the culmination of all procedures prior to the placing of the product on the market.

[4] For further information, please consult the document Communication from the Commission "*Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745*", *OJ C 171, 19.5.2020, p. 1–4.*

In the case of some medical devices, the manufacture may affix this marking, without necessarily involving a notified body in the conformity assessment procedure (c.f. paragraph 1 of Q6 above). However, no CE marking is affixed on medical devices, which have received authorisation to be placed on the market under a national derogation pursuant to Article 11(13) of Directive 93/42/EEC or Article 59 of Regulation (EU) 2017/745.[5]

In the case of PPE items, the CE marking should normally be affixed by the manufacturer once the first sample of the product has been assessed and approved by the notified body (c.f. paragraph 2 of Q6 above). In the specific COVID-19 context however, there might be derogations to this requirement in specific circumstances (c.f. Q5 above).

Please note that according to both legal frameworks, the CE marking should be affixed on each individual item.

Q8: Are there any specifications as to the exact materials to be used to manufacture face masks?

Neither the applicable EU legal frameworks, nor the harmonised standards EN 149 and EN 14683 impose any mandatory specifications as to the materials to be used. The legal frameworks essentially introduce performance requirements, which are further detailed by the relevant standards. Therefore, manufacturers retain full choice as to the type of materials they can use.

In practice, in the case of **FFP-type face masks**, the following materials tend to be the most popular choice:

- Filter layer: polypropylene;
- Valve (*if applicable*): rubber or polypropylene;
- Straps: polyester, polyisoprene,;
- Seal: polyethylene foam, polyurethane etc.;
- Clips/staples (*if applicable*): aluminium, steel.

In the case of surgical masks, the material of choice tends to be a nonwoven material (S-M-S type) using a combination of melt-blown and spun-bond fabrics. The fabrics are usually based on polypropylene.

Q9: What are the necessary documents, which must accompany items of PPE or medical devices placed 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, only such documents which are explicitly referred to in the relevant EU legal framework may be used for the purpose of demonstrating compliance of the said product with the applicable legal requirements.

[5] For further information, please consult the document Communication from the Commission "*Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745*", *OJ C 171, 19.5.2020, p. 1–4.*

The recent practice has highlighted examples of documents which have no legal status according to the applicable EU legislation. These may in some cases accompany PPE or medical devices intended to be placed on the market. Such documents may be entitled "certificate of compliance", "attestation of compliance", "certificate of conformity", "certificate of notification", "certificate of registration", "documentation review" or carry a similar title. They are sometimes also presented as "voluntary certificates". Such documents do not comply with the requirements of EU legislation as to the content of an EC or EU declaration of conformity issued by the manufacturer or a certificate issued by a notified body. Therefore, such alternative documents do not constitute a proof that the product in question has been successfully subjected to the mandatory conformity assessment procedures and is thus safe and compliant with the applicable legal requirements.

For more information, please consult the document "*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*" as well as the relevant provisions of Council Directive 93/42/EEC on medical devices (Articles 11 and 17 *inter alia*) and Regulation (EU) 2016/425 on PPE (Chapter III 'Conformity of the PPE' *inter alia*).

Q10: How can I verify whether a certificate issued by a conformity assessment body is authentic?

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. A product certificate 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). A quality management system certificate 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 are entitled to issue valid certificates, within their scope and competences.

A conformity assessment body must be notified under each specific EU legislative act in order to be able to perform certain conformity assessment procedure(s) for specific types of products under the said legislative act, as indicated in the notification. 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, it is not automatically allowed to perform conformity assessment procedures under other EU legislative act(s) or for different scope and competences. A separate notification would have to be requested for this, even if the notified body always keeps 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 PPE 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 for the specific EU legislative act(s), irrespective of the Member State in which the notified body is located. Please note that notified bodies shall be located only within the territories of one of the EU Member States, as well as the EEA countries, Switzerland (by virtue of the Mutual Recognition Agreement with the EU) and Turkey (by virtue of the Customs Union Agreement with the EU).

Every certificate issued by a notified body prior to placing PPE or medical devices on the EU market must specify the conformity assessment procedure applied. It 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.

Please find below the links to the relevant lists of notified bodies in the NANDO database:

- List of notified bodies under the Regulation (EU) 2016/425 on PPE;
- List of notified bodies under Council Directive 93/42/EEC on medical devices;
- List of notified bodies under Regulation (EU) 2017/745 on medical devices.

For more information, please consult the document "*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*".