II

(Non-legislative acts)

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2020/403

of 13 March 2020

on conformity assessment and market surveillance procedures within the context of the COVID-19 threat

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) In the context of the current COVID-19 global outbreak as well as the rapid spread of the virus across various regions of the EU, the demand for personal protective equipment (hereinafter 'PPE') such as face masks, gloves, protective coveralls or eyewear protection, as well as for medical devices such as surgical masks, exploration gloves and some gowns, has seen an exponential growth. In particular, the supply chain of certain types of PPE such as the disposable face masks is under severe strain, due to the exponential growth of the demand both via existing as well as via new channels. In addition, the global supply chain of such products has also sustained significant disruptions, which have induced repercussions on the EU market as well.

(2) Bearing in mind that the health and safety of the EU citizens is of upmost priority, it is of paramount importance to ensure that the most appropriate PPE and medical devices ensuring adequate protection are swiftly made available to those who need it most.

(3) Economic operators active across the EU are working relentlessly to increase their respective manufacturing and distribution capacity. In order to mitigate the effects of the various disruptive factors, the economic operators are redesigning their supply chains by launching new manufacturing lines and/or diversifying their supplier base. These efforts by the industrial stakeholders would not be able to produce their full effects if the increased supply cannot feed into the market without any undue delays.

(4) The requirements for the design, manufacturing and placing on the market of personal protective equipment are laid down 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 ([1]).

(5) The requirements for the design, manufacturing and placing on the market of medical devices are laid down by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([2]). That Directive is repealed by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No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 ([3]), with effect from 26 May 2020.

(6) Disposable and re-usable face masks ensuring protection against particulate hazards, disposable and re-usable coveralls, gloves and eyewear protection, which are used for prevention and protection against harmful biological agents such as viruses are products falling within the scope of the Regulation (EU) 2016/425.

([1]) 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, OJ L 81, 31.3.2016, p. 51.
([2]) OJ L 169, 12.7.1993, p. 1.
([3]) OJ L 117, 5.5.2017, p. 1.

(7) Surgical masks, examination gloves and some types of gowns are products falling within the scope of Directive 93/42/EEC and of Regulation (EU) 2017/745.

(8) In the context of the COVID-19 threat, such PPE and medical devices are essential for healthcare workers, first responders and other personnel involved in the efforts to contain the virus and avoid its further spread.

(9) Regulation (EU) 2016/425 fully harmonises the rules for the design, manufacturing and placing on the Union market of PPE and sets out a number of essential health and safety requirements for PPE based on a classification of PPE depending on the risk against which it is intended to protect users. Thus, items of PPE manufactured in accordance with the Regulation (EU) 2016/425 can circulate freely throughout the internal market and Member States may not introduce additional and diverging requirements regarding the manufacturing and placement on the market of such products.

(10) Directive 93/42/EEC and Regulation (EU) 2017/745 fully harmonise the rules for the design, manufacturing and placing the Union market of medical devices, and set up a number of essential requirements and of general safety and performance requirements, based on a classification of medical devices depending on specific rules governed by the intended purpose of the devices. Thus, devices manufactured in accordance with the Council Directive 93/42/EEC and Regulation (EU) 2017/745 can circulate freely throughout the internal market and Member States may not introduce additional and diverging requirements regarding the manufacturing and placement on the market of such products.

(11) PPE intended to protect against harmful biological agents, such as viruses are listed in Annex I of Regulation (EU) 2016/425 as category III, which includes exclusively the risks that may cause '*very serious consequences such as death or irreversible damage to health*'.

(12) Relevant medical devices as non-invasive devices are in Class I, unless specific rules apply.

(13) In accordance with Article 8 of Regulation (EU) 2016/425, in order to place PPE products on the market, manufacturers shall carry out the applicable conformity assessment procedures and, where compliance with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, affix the CE marking.

(14) In accordance with Article 11 of Directive 93/42/EEC and with Article 52 of Regulation (EU) 2017/745, once the latter becomes applicable, in order to place medical devices on the market, manufacturers shall carry out the applicable conformity assessment procedures and, where compliance with the applicable essential requirements or general safety and performance requirements has been demonstrated by the appropriate procedure, affix the CE marking. Derogations from conformity assessment procedures may be authorised by Member States, on duly justified request, for the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices the use of which is in the interest of protection of health.

(15) Regulation (EU) 2016/425 is technologically neutral and does not lay down any specific mandatory technical solutions for the design of PPE products. Instead, Annex II to Regulation (EU) 2016/425 sets the essential health and safety requirements, which PPE should meet in order to be able to be placed on the market and to circulate freely across the entire EU market.

(16) Directive 93/42/EEC and Regulation (EU) 2017/745 are technologically neutral and do not lay down any specific mandatory technical solutions for the design of medical devices. Instead, Annex I to Directive 93/42/EEC sets the essential requirements, and Annex I to Regulation (EU) 2017/745 sets the general safety and performance requirements, which medical devices should meet in order to be able to be placed on the market and to circulate freely across the entire EU market.

(17) Article 14 of Regulation (EU) 2016/425 offers the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*. In accordance with this Article, should a manufacturer choose to adopt such a technical solution, the PPE is presumed to be in conformity with the essential health and safety requirements covered by the said harmonised standard or parts thereof. However, compliance with the harmonised standards is not mandatory. Manufacturers are free to choose other technical solutions provided that the specific solution which is retained ensures that the PPE complies with the applicable essential health and safety requirements.

(18) Article 5 of Directive 93/42/EEC and Article 8 of Regulation (EU) 2017/745 offer the possibility for manufacturers to rely on specific technical solutions, which are detailed in harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*. In accordance with this Article, should a manufacturer choose to adopt such a technical solution, the medical device is presumed to be in conformity with the requirements covered by the said harmonised standard or parts thereof. However, compliance with the harmonised standards is not mandatory. Manufacturers are free to choose other technical solutions provided that the specific solution which is retained ensures that the medical device complies with the applicable essential health and safety requirements.

(19) Article 19 of Regulation (EU) 2016/425 lays down the specific conformity assessment procedures, which apply to the different categories of PPE. Pursuant to this Article, items of PPE of category III, such as the ones designed protect against harmful biological agents should be subjected to specific combination of conformity assessment procedures, which are described respectively in Annexes V, VII and VIII of the same Regulation. Each of the different conformity assessment procedures, which may be used, require the mandatory involvement of a third party conformity assessment body.

(20) Article 11 of Directive 93/42/EEC and Article 52 of Regulation (EU) 2017/745, once the latter becomes applicable, lay down the specific conformity assessment procedures, which apply to the different classes of medical devices. Pursuant to these Articles, medical devices falling within Class I, other than custom-made or investigational devices, should be subjected to the conformity assessment procedure for the EC declaration of conformity, without the involvement of a third party conformity assessment body.

(21) Notified bodies are the conformity assessment bodies designated by Member States and authorised to carry out third party conformity assessment tasks under Regulation (EU) 2016/425. According to Article 26(4) and point 7 (f) of Annex V of Regulation (EU) 2016/425, notified bodies are required to assess that a PPE product meets the applicable essential health and safety requirements. Notified bodies need to carry out this assessment not only where the manufacturer has applied the harmonised standards, but also in a situation where the manufacturer has followed other technical solutions. When delivering the conformity assessment certificates, notified bodies are required to inform their notifying authorities and may also be required to inform other notified bodies of the certificates they have issued, as set out in Article 34 of Regulation (EU) 2016/425.

(22) Notified bodies should thus assess whether products manufactured in line with other technical solutions, such as the ones contained in the WHO recommendations on the appropriate selection of PPE also meet the applicable essential health and safety requirements. In view of the importance to ensure an efficient exchange of information between all stakeholders in the PPE supply chain, where notified bodies conclude that a PPE following another specific standard or technical solution is compliant with the essential health and safety requirements applicable to it, sharing this information will be instrumental in facilitating the assessment of other products manufactured according to the same specific standard or technical solution in a swift manner. To that effect, notified bodies can make use of the existing channels for exchange of information in the framework of the coordination groups established in accordance with Article 36 of Regulation (EU) 2016/425.

(23) In addition, pursuant to the relevant market surveillance procedures in Regulation (EU) 2016/425 and in particular Article 38(1) and (2) thereof, where a market surveillance authority encounters a non-CE marked PPE product they are required to evaluate it. Where, in the course of the evaluation, the market surveillance authorities find that the PPE does not comply with the requirements laid down in the Regulation, they shall require the economic operator to take corrective action to bring the PPE into compliance or to recall or withdraw it, commensurate with the nature of the risk. They shall also inform the Commission and other Member State of the results of the evaluation and the actions which they have required the economic operator to take.

(24) Accordingly, to address the shortage of PPE necessary in the context of the COVID-19 outbreak, where non-CE marked PPE are intended to enter the EU market, the relevant market surveillance authorities should evaluate the products and, if they are found to be compliant with the essential health and safety requirements laid down by the relevant Regulation should take measures allowing the placing of such PPE on the Union market for a limited period of time or while the conformity assessment procedure with the notified body is being carried out. In order to ensure that such products can be made available in other Member States and in view of the importance to ensure an efficient exchange of information as well as a coordinated response to all threats to the citizens' health and safety, it is appropriate that the market surveillance authority carrying out such an evaluation communicates its decision to other Member States authorities and to the Commission through the regular market surveillance information exchange channels.

(25) Considering that certain types of PPE or medical devices that are used in the context of the COVID-19 outbreak, may also be used for other purposes, it is necessary that Member States take all appropriate measures to ensure that PPE or medical devices not bearing the CE marking, which may be placed on the Union market in accordance with paragraph 8 of the present Recommendation are only made available to healthcare workers,

HAS ADOPTED THIS RECOMMENDATION:

1. With the objective to ensure availability of PPE and medical devices for adequate protection in the COVID-19 outbreak, the Commission invites all economic operators throughout the supply chain, as well as notified bodies and market surveillance authorities to deploy all the measures at their disposal to support the efforts aimed at ensuring that the supply of PPE and medical devices throughout the EU market will match the continuously increasing demand. Such measures should nevertheless not have a detrimental effect on the overall level of health and safety and all relevant stakeholders should ensure that any PPE or medical devices, which is being placed on the EU market, continues to provide an adequate level of protection of the users' health and safety.

CONFORMITY ASSESSMENT PROCEDURES

2. The notified bodies under Regulation (EU) 2016/425 should prioritise and swiftly conduct the conformity assessment activities in the framework of all newly submitted requests by economic operators of PPE necessary for protection in the context of the COVID-19 outbreak.

3. In the case of PPE products manufactured following technical solutions other than harmonised standards, the WHO recommendations on the appropriate selection of PPE may be used as a potential source of reference for such technical solutions, provided that the said technical solutions ensure an adequate level of protection corresponding to the applicable essential health and safety requirements laid down in Regulation (EU) 2016/425.

4. Notified bodies which issue certificates to PPE products manufactured following other technical solutions than harmonised standards, should immediately inform the relevant notifying authority as well as the other notified bodies under Regulation (EU) 2016/425 of the certificates issued and the specific technical solution followed. Notified bodies should exchange such information through the coordination of notified bodies group established under Article 36 of Regulation (EU) 2016/425.

5. In the case of medical devices, the possibility for Member States to authorise derogations from conformity assessment procedures should also be considered, according to Article 11(13) of Directive 93/42/EEC and Article 59 of Regulation (EU) 2017/745 once the latter becomes applicable, also when the intervention of a notified body is not required.

MARKET SURVEILLANCE PROCEDURES

6. The relevant market surveillance authorities in the Member States should as a matter of priority focus on non-compliant PPE or medical devices raising serious risks as to the health and safety of their intended users.

7. Where market surveillance authorities find that PPE or medical devices ensure an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC or Regulation (EU) 2017/745, even though the conformity assessment procedures, including the affixing of CE marking have not been fully finalised according to the harmonised rules, 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.

8. PPE or medical devices not bearing the CE marking could also be assessed and part of a purchase organised by the relevant Member State authorities provided that is ensured that such products are only available for the healthcare workers for the duration of the current health crisis and that they are not entering the regular distribution channels and made available to other users.

9. Market surveillance authorities should inform immediately the Commission and other Member States of any temporary arrangement they have granted to specific PPE or medical devices. For PPE, this should be done through the Information and Communication System for Market Surveillance (ICSMS).

Done at Brussels, 13 March 2020.

For the Commission
Thierry BRETON
Member of the Commission