

Official Journal of the European Union

L 310



English edition

Legislation

Volume 64

2 September 2021

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II

(Non-legislative acts)

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2021/1433

of 1 September 2021

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 beginning of 2020, the COVID-19 pandemic triggered an unprecedented and exponential growth in the demand on the EU market 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. In particular, the supply chain of certain types of PPE such as the disposable face masks was put under severe strain. 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) Economic operators active across the EU have been working relentlessly to increase their respective manufacturing and distribution capacity. In order to mitigate the effects of the various disruptive factors, the economic operators have often redesigned their supply chains by launching new manufacturing lines and/or diversifying their supplier base.
- (3) 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⁾.
- (4) The requirements for the design, manufacturing and placing on the market of medical devices are laid down 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(EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ⁽²⁾, that repealed Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽³⁾ with effect from 26 May 2021.
- (5) 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.
- (6) Surgical masks, examination gloves and some types of gowns are products falling within the scope of Regulation (EU) 2017/745 and of the repealed Directive 93/42/EEC.

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

- (7) In the context of the COVID-19 threat, such PPE and medical devices have proven to be essential for healthcare workers, first responders and other personnel involved in the efforts to contain the virus and avoid its further spread.
- (8) 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.
- (9) Regulation (EU) 2017/745, as well as the repealed Directive 93/42/EEC, fully harmonises the rules for the design, manufacturing and placing on the Union market of medical devices, and set up a number 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 Regulation (EU) 2017/745 and Directive 93/42/EEC under certain conditions 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) PPE intended to protect against harmful biological agents, such as viruses are listed in Annex I to 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'.
- (11) Medical devices as non-invasive devices are in Class I, unless specific rules apply.
- (12) 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.
- (13) In accordance with Article 52 of Regulation (EU) 2017/745 and with Article 11 of the repealed Directive 93/42/EEC, in order to place medical devices on the market, manufacturers shall carry out the applicable conformity assessment procedures and, where compliance with the applicable general safety and performance requirements has been demonstrated by the appropriate procedure, affix the CE marking. Derogations from the conformity assessment procedures may be authorized by Member States, on a duly justified request, for the placing on the market and putting into service within the territory of the Member State concerned, of specific devices the use of which is in the interest of public health or patient safety or health.
- (14) 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.
- (15) Regulation (EU) 2017/745, as well as the repealed Directive 93/42/EEC, is technologically neutral and does not lay down any specific mandatory technical solutions for the design of medical devices. Instead, 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.
- (16) 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 to 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.

- (17) Article 52 of Regulation (EU) 2017/745 lays down the specific conformity assessment procedures, which apply to the different classes of medical devices. Pursuant to this Article, medical devices falling within Class I, other than custom-made or investigational devices, should be subjected to the conformity assessment procedure for the EU declaration of conformity, without the involvement of a third party conformity assessment body.
- (18) 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 24(6) and point 4 (f) of Annex V to Regulation (EU) 2016/425, notified bodies are required to assess that a PPE product meets the applicable essential health and safety requirements.
- (19) 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 the other Member States of the results of the evaluation and the actions which they have required the economic operator to take, if they consider that the non-compliance is not restricted to the national territory.
- (20) In order to allow for the increased supply of PPE and medical devices to feed into the market swiftly and without undue delays, on 13 March 2020 the Commission adopted Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat ⁽⁴⁾.
- (21) With respect to the conformity assessment procedures for PPE products and medical devices, Recommendation (EU) 2020/403 urged the notified bodies under Regulation (EU) 2016/425 to 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.

Furthermore, Recommendation (EU) 2020/403 reminded that technical solutions other than harmonised standards may be used for designing PPE products, 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. In that respect, the WHO recommendations on the appropriate selection of PPE were identified as a potential source of reference for such technical solutions.

- (22) With respect to PPE or medical devices, which have not undergone the conformity assessment procedures prescribed in Article 19 of Regulation (EU) 2016/425 or in Article 52 of Regulation (EU) 2017/745, Recommendation (EU) 2020/403 entrusted the market surveillance authorities in the Member States with two distinct mechanisms.
- (23) On the one hand, in accordance with point 7 of Recommendation (EU) 2020/403, 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.
- (24) On the other hand, 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.

⁽⁴⁾ OJ L 79I, 16.3.2020, p. 1.

- (25) Furthermore, pursuant to point 9 of Recommendation (EU) 2020/403, market surveillance authorities should inform immediately the Commission and the 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).
- (26) Finally, Recommendation (EU) 2020/403 reminded that the relevant market surveillance authorities 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.
- (27) Since March 2020, a number of market surveillance authorities have made use of the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403. In particular, certain national market surveillance authorities developed specific testing protocols and enshrined the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403 into their respective national legal order. Most often this was done in the framework of national legal instruments organising the COVID-19 response at national level.
- (28) Since the beginning of the COVID-19 pandemic, the Commission has been closely monitoring the state of the supply chains for PPE and medical devices. In this context, the Commission is maintaining continuous contacts with all Member States market surveillance authorities and relevant stakeholders such as notified bodies, economic operators as well as consumer, user and patient associations.
- (29) Based on the information gathered both from industrial stakeholders as well as from the relevant national authorities, it can be concluded that there are no longer any significant shortages of PPE and medical devices on the EU market and it is to be expected that the situation would remain stable.
- (30) The objective of Recommendation (EU) 2020/403 has been to enable a swifter placement on the EU market of essential PPE and medical devices used in the COVID-19 context in order to contribute to the array of measures deployed in view of increasing the supply and availability of such essential PPE and medical devices.
- (31) Considering that for the past several months there have not been any drastic fluctuations in the supply or demand for essential PPE and medical devices used in the COVID-19 context and in view of the prospects of a stable evolution of the supply and demand, the underlying conditions justifying the application of Recommendation (EU) 2020/403 are no longer reunited. It is therefore appropriate to discontinue in particular the application of the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403.
- (32) In order to ensure legal certainty and in particular in order to provide the national market surveillance authorities and the concerned economic operators with sufficient time to adjust, it is appropriate to defer the date as from which the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403 would cease to apply.
- (33) PPE or medical devices, which have been assessed by a market surveillance authority in accordance with the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403 and in relation to which the competent market surveillance authority has issued an approval decision, have been proven to comply with the essential health and safety requirements laid down in Annex II to Regulation (EU) 2016/425 or in Annex I to Regulation (EU) 2017/745 or in Annex I to the repealed Directive 93/42/EEC. In order to allow any potential stocks of PPE or medical devices which have proven to provide an adequate level of protection of the users' health and safety to be absorbed and used up by the end users, and in order to ensure legal certainty, it is appropriate to defer the date as from which products approved pursuant to the mechanisms described in points 7 and 8 of Recommendation (EU) 2020/403 may no longer be made available to end users. Past this date, no PPE or medical devices should be made available on the EU market unless it has undergone the mandatory conformity assessment procedures and has been lawfully affixed with the CE marking, or, in the case of medical devices, unless specific derogations from the conformity assessment procedure have been authorised by Member States according to Article 59 of Regulation (EU) 2017/745.

- (34) The objective of the mechanism described in point 8 of Recommendation (EU) 2020/403 has been to ensure that essential PPE and medical devices are swiftly made available to healthcare workers. Bearing in mind the considerable demand for PPE and medical devices generated by the healthcare sector in the context of the COVID-19 pandemic, it cannot be excluded that over the past months certain healthcare facilities may have generated certain stocks of PPE products and medical devices, which have been granted with an approval decision on the basis of the mechanism described in point 8 of Recommendation (EU) 2020/403. It can reasonably be expected that the demand for essential PPE products and medical devices generated by the healthcare sector will remain strong for the total duration of the COVID-19 pandemic. In order to avoid the risk of creating distortions in the supply of essential PPE and medical devices for the benefit of healthcare workers, it is appropriate to ensure that healthcare facilities and first responders can use up all the concerned PPE products and medical devices which have been proven to be compliant with the essential health and safety requirements laid down in Annex II to Regulation (EU) 2016/425 or in Annex I to Regulation (EU) 2017/745 or in Annex I to the repealed Directive 93/42/EEC, including those products assessed in accordance with the mechanism described in point 8 of Recommendation (EU) 2020/403.

HAS ADOPTED THIS RECOMMENDATION:

Market surveillance procedures

1. As from 1 October 2021, market surveillance authorities should no longer authorise PPE, which have not successfully undergone the relevant conformity assessment procedures in accordance with Article 19 of Regulation (EU) 2016/425. PPE authorised by market surveillance authorities in accordance with the mechanisms described in points 7 or 8 of Commission Recommendation (EU) 2020/403 cannot be placed on the Union market after 1 October 2021.
2. Market surveillance authorities may authorise medical devices, which have not successfully undergone the relevant conformity assessment procedures in accordance with Article 52 of Regulation (EU) 2017/745, to be made available on the Union market, only by following the procedure for derogations from the conformity assessment procedures laid down in Article 59 of Regulation (EU) 2017/745.
3. PPE or medical devices, which have been granted an authorisation by a market surveillance authority in accordance with the mechanisms described in point 7 or 8 of Commission Recommendation (EU) 2020/403, shall only be made available until 31 May 2022. By means of exception, any such PPE or medical device, which is part of existing stocks at the disposal of healthcare workers, first responders and other personnel involved in the efforts to contain the virus and avoid its further spread may be made available until such stocks are fully exhausted but in any event no later than 31 July 2022.
4. The market surveillance authorities in the Member States should continue to focus as a matter of priority on non-compliant PPE or medical devices raising serious risks as to the health and safety of their users. In particular, as from 1 August 2022, market surveillance authorities should ensure all PPE or medical devices, which have been placed on the EU market have successfully passed the relevant conformity assessment procedures in accordance with Article 19 of Regulation (EU) 2016/425 or Article 52 of Regulation (EU) 2017/745 and bear a lawfully affixed CE marking, in accordance with Article 17 of Regulation (EU) 2016/425 or Article 20 of Regulation (EU) 2017/745, unless, in the case of medical devices, specific derogations from the conformity assessment procedure have been authorised by Member States according to Article 59 of Regulation (EU) 2017/745.
5. Market surveillance authorities should inform immediately the Commission and the other Member States of all cases in which they identify a non-compliant PPE product or medical device. For PPE, this should be done through the Information and Communication System for Market Surveillance (ICSMS). If products are found to be unsafe and measures are taken against such products that do not adequately protect, Market Surveillances Authorities should notify them in the rapid alert system for dangerous non-food products (Safety Gate/RAPEX).

6. Whenever they identify a non-compliant PPE product or medical device, market surveillance authorities should immediately set in motion the relevant procedures laid down in Chapter VI of Regulation (EU) 2016/425 or Chapter VII of Regulation (EU) 2017/745.

Done at Brussels, 1 September 2021.

For the Commission
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Member of the Commission

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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