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To:	Permanent Representatives Committee
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Subject:	Regulation on the Single Market Emergency Instrument Regulation amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures due to a Single Market emergency Directive amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures due to a Single Market emergency. - Analysis of the final compromise text with a view to agreement

2022/0279 (COD)

▌

▌REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL▐

amending Regulations *(EU) No 305/2011,* **(EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU)** *2023/988 and (EU) 2023/1230* **as regards emergency procedures for the conformity assessment,** *presumption of conformity,* **adoption of common specifications and market surveillance due to** *an internal* **market emergency**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

[1] OJ C , , p. .

[2] Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.

Whereas:

(1) [insert reference to ***IMERA*** Regulation] aims to ensure the normal functioning of the ***internal*** market, including the free movement of goods, services and persons and ***ensure*** the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.

(2) The framework established by [insert reference to ***IMERA*** Regulation] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the ***internal*** market that a crisis may cause.

(3) [insert reference to ***IMERA*** Regulation] lays down a multi-layered mechanism consisting of contingency planning, ***and internal*** market ***vigilance and*** emergency ***modes***.

(4) [insert reference to ***IMERA*** Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the ***internal*** market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to ***IMERA*** Regulation] applies to both goods and services.

(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that ***crisis-relevant goods*** referred to in [insert reference to ***IMERA*** Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.

(6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424[3], (EU) 2016/425[4], (EU) 2016/426[5],[6] ***(EU) No 305/2011[7] and (EU) No 2023/1230[8]*** of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) ***No 2023/1230*** are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council[9]**.**

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3 OJ L 81, 31.3.2016, p. 1.
4 OJ L 81, 31.3.2016, p. 51.
5 OJ L 81, 31.3.2016, p. 99.
6 ***OJ L 170, 25.6.2019, p. 1.***
7 ***OJ L 88, 4.4.2011, p. 5.***
8 ***OJ L 165, 29.6.2023, p 1.***
9 ***OJ L 218, 13.8.2008, p. 82.***

(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral ***Union*** harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.

(8) Experience from the recent crises that have affected the ***internal*** market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to ***IMERA*** Regulation].

(8a) Non-harmonised products can also be crisis-relevant goods. Therefore, some of the relevant mechanisms under this Regulation, notably the presumption of safety based on national requirements, national or international standards, could provide an additional avenue to establish the presumption of safety of non-harmonised crisis-relevant goods during the crisis. This would facilitate the placing on the market of non-harmonised crisis-relevant goods in times of crisis.

(9) In order to overcome the potential effects of disruptions on the ***internal*** market and in order to ensure that ***harmonised*** crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. ***In the context of such prioritisation, no additional disproportionate costs may be charged by the conformity assessment body to the manufacturer. All additional costs charged by a conformity assessment body to the manufacturer should be strictly proportionate to the actual additional efforts deployed by the conformity assessment body to implement the prioritisation and should be limited to the period of application of the internal market emergency. The transfer of certain additional and proportionate costs by the conformity assessment bodies to the manufacturers should remain exceptional and should reflect a fair distribution of the costs among all the stakeholders involved in the efforts to contain the disruptions to the functioning of the internal market. The costs associated with conformity assessment should not become a barrier to the entry on the market of prospective new manufacturers, in particular SMEs and should not restrict the emergence of innovative products. Furthermore, the notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.***

(10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ***No 305/2011, (EU) 2023/988 and (EU) 2023/1230***. Those procedures should be available only following the activation of the ***internal*** market emergency mode in accordance with [***insert reference to IMERA Regulation***].

(11) Furthermore, in cases***, for example,*** where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective ***Union*** sectoral ***harmonisation*** legislation.

(12) As regards products falling within the scope of those ***harmonisation*** Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing ***internal*** market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, ▌ where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they ***ensure the conformity*** with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures ▌ which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.

(12a) Since the essential safety requirements harmonised by the existing Regulations remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union by means of implementing acts unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby to maintain consumer confidence in the safety of products bearing the CE marking in the Union market. Therefore, these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected. By providing an additional, parallel avenue for exceptionally placing crisis-relevant goods on the market in the context of an internal market emergency, the derogatory rules enable new manufacturers to swiftly place their products on the market without the need to wait for the finalisation of the normal conformity assessment procedures. Such an accelerated and exceptional placing on the market contributes to the swift increase in the supply of crisis-relevant goods and at the same time provides the manufacturers with a facilitation as it allows them to place initial batches or series of products on the market before the conclusion of the conformity assessment procedures.

Once the conformity assessment procedures have been successfully completed, subsequent batches or series of products should be fully compliant with the relevant, applicable rules and thus benefit from free movement. The co-existence during an internal market emergency of an exceptional, derogatory set of rules alongside the existing rules thus makes it possible to transition towards the existing rules, enabling the manufacturers to continue placing their products on the market after the expiry or deactivation of the internal market emergency mode.

(12b) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. That implementing act can provide that the benefit of the free movement is also granted to goods already placed on the market on the basis of pre-existing authorisation. All pre-existing authorisations adopted by Member States prior to the entry into force of the Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry into force of the Commission implementing act concerning the same goods and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in corrective or restrictive actions to be taken by the Commission by means of another implementing act.

(12c) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active internal market emergency mode, as referred to in the IMERA Regulation, should automatically expire on the date of expiry or deactivation of the internal market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant goods on the market should occur on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that the goods covered by such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive measures at their disposal in accordance with the provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011, (EU) 2023/1230 and Regulation (EU) 2019/1020. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in accordance with the relevant sectorial emergency procedures.

(12d) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-relevant goods. The Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespectively whether those measures have to be notified or not in Safety Gate due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.

(12e) All authorisations for the placing on the market of crisis-relevant goods issued by Member States should contain at least certain elements which substantiate the assessment of the compliance of the good in question with the applicable essential requirements and which allow to ensure traceability. The relevant elements concerning the traceability include specific requirements regarding the labelling, accompanying documents or any additional means of ensuring the identification of the goods concerned and allowing to trace them along the supply chain. In order to ensure uniform and coherent implementation of the traceability requirements across the Union, Commission implementing acts extending the validity of authorisations issued by a Member State should also specify the common traceability requirements. These include the specific arrangements regarding the indication that the product concerned is a 'crisis-relevant good'. On expiry of the internal market emergency mode, the Commission should be empowered to adopt via implementing acts any necessary adjustments to the traceability requirements for crisis-relevant products that have already been placed on the market on the basis of an authorisation issued by a Member State.

(13) Where ***an internal*** market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods ▌ which comply with the applicable essential health and safety requirements.

(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. ***The Union general product safety framework established by Regulation (EU) 2023/988 also establishes under certain conditions a mechanism of presumption of conformity with the general safety requirement where a product complies with relevant European standards, the references of which have been published in the Official Journal of the European Union.*** However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative ***crisis-response*** mechanisms.

(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and ***(EU) 2023/1230*** the competent national authorities should be able to presume that products manufactured in accordance with ***European or*** national ***standards of the Member States, or with relevant*** international standards ***developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and*** ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant ***and applicable*** essential ***requirements. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the implementing act listing the European, relevant and applicable international or the national standards of the Member States. In cases where there are concerns regarding the compliance of a harmonised crisis-relevant product placed on the market during an internal market emergency on the basis of a presumption of conformity established via such an implementing act, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act, compliance with the European, relevant and applicable international or the national standards of the Member States should no longer provide a presumption of conformity with the relevant and applicable essential*** requirements.

(15a) With respect to Regulation (EU) 2023/988, under the competent national authorities should be able to presume that products manufactured in accordance with European or national standards of the Member States, or with relevant international standards developed by a recognised international standardisation body comply with the general safety requirement. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the internal market emergency mode. Where there is evidence that the crisis-relevant non-harmonised product placed on the market during an internal market emergency on the basis of the presumption of conformity established via these emergency procedures is dangerous, the market surveillance authorities should be allowed to take all appropriate measures under Regulation (EU) 2023/988. After the expiry or deactivation of the internal market emergency mode a demonstration of compliance with the said European, relevant and applicable international, or national standards of the Member States should no longer provide a presumption of conformity with the general safety requirement.

(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 ***and (EU) 2023/1230***, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the ***internal*** market emergency. ***Products placed on the market on the basis of the presumption of conformity established via the demonstration of compliance with these common specifications should not be withdrawn automatically simply as a result of the expiry or withdrawal of the implementing act laying down the said common specifications. In cases where there are concerns regarding the compliance of a crisis-relevant product placed on the market during an internal market emergency on the basis of the presumption of conformity established via the demonstration of compliance with common specifications, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act laying down the common specifications a demonstration of compliance with the said common specifications should no longer provide a presumption of conformity with the relevant and applicable essential requirements.***

▌

(18) In order to ensure that the level of safety provided by the harmonised ***and non-harmonised*** products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.

(18a) In accordance with the relevant provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority.

(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.

(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ***No 305/2011, (EU) 2023/988 and (EU) 2023/1230*** should therefore be amended accordingly**.**

(21) In order for this Regulation to apply from the same date as ***IMERA*** Regulation ▌ , its application should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2016/424

▌ Regulation (EU) 2016/424 ***is amended as follows***:

(1) In Article 3 the following points are added:

'***(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(29) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;'

(2) The following Chapter Va is inserted after Chapter V:

'Chapter Va

▌ EMERGENCY PROCEDURES

Article 43a

▌ Application of emergency procedures

1. Articles 43b to 43g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of ***the IMERA*** Regulation.

2. Articles 43b to 43g shall apply exclusively to subsystems and safety components ▌ which have been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

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3. Articles 43b to 43g, except as regards ***the power*** of the Commission ***in Article 43e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

   However, Article 43 ▌ c(5) shall apply during the ***internal*** market emergency mode and after its deactivation or expiry ▌

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to subsystems and safety components placed on the market in accordance with Articles 43c to ***43e***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 43b

▌ Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components

1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.

2. The notified bodies shall ***make best efforts to*** process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority***, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a***.

▌

4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified. ▌

Article 43c

Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article 18, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or the incorporation into a cableway installation within the territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated ***in accordance with procedures referred to in that authorisation***.

1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific subsystem or safety component may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).

The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ▌ competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation***. The authorisations shall at least set out the following***:

   (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;

   (b) ***any*** specific requirements regarding the traceability of the subsystem or safety component concerned;

   (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA Regulation***;

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;

(e) measures to be taken ▌ upon expiry of the ***internal market emergency with respect to*** the subsystem or safety component ***placed on the market***.

▌

5. By way of derogation from Articles 7***, 20 and 21***, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and Article 7*** shall not ***apply***.

5a. The market surveillance authorities of ***a*** Member State, ***where*** an authorisation pursuant to ***paragraphs 1, 1a and 1c is valid,*** shall be entitled to take all corrective and restrictive ***actions*** at national level provided for ***under Regulation (EU) 2019/1020 and*** under this Regulation with respect to such subsystems or safety components.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

▌

8. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned. ▌

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Article 43e

Presumption of conformity based on standards and common specifications

1. Where subsystems and safety components ▌ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:

   (a) ▌ no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the ***Official Journal of the European Union*** in accordance with Regulation (EU) No 1025/2012***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** market, which led to the activation of the ***internal*** market emergency mode in accordance with Article 14 of ***the IMERA*** Regulation ▌ , significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II ▌ and already published in the ***Official Journal of the European Union*** in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

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2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 44(3) and they shall apply ▌ until the last day of the period for which the ***internal*** market emergency mode remains active***, unless amended or repealed in accordance with paragraph 5***.

2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 17, subsystems and safety components which are in conformity with ***the standards or*** common specifications ***referred to in*** paragraph ***1, or parts thereof,*** shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 43a(3), ▌ unless there is sufficient reason to believe that the subsystems or safety components covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the subsystems or safety components ***which are in conformity with those standards or*** common specifications ***and*** which have been placed on the market shall be deemed compliant with ***the essential requirements set out in Annex II*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** Regulation ▌ .

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the essential requirements ▌ set out in Annex II, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

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Article 43g

▌ Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods. ***The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***

2. The market surveillance authorities of the Member States shall ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. ’▌

PUBLIC

Article 2

Amendments to Regulation (EU) 2016/425

Regulation (EU) 2016/425 ***is amended as follows***:

(1) In Article 3 the following points are added:

'***(19) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(20) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;'

(2) The following Chapter VIa is inserted after Chapter VI:

'Chapter VIa

EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures

1. Articles 41b to 41g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of ***the IMERA*** Regulation.

2. Articles 41b to 41g apply exclusively to PPE, which has been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

3. Articles 41b to 41g, except as regards ***the power*** of the Commission ***in Article 41e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

   However, Article 41 c(5) shall apply during the ***internal*** market emergency mode and after its deactivation or expiry.

PUBLIC

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to PPE placed on the market in accordance with Articles 41c to ***41e. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). ▌

Article 41b

▌ Prioritisation of the conformity assessment of crisis-relevant PPE

1. This Article shall apply to PPE designated as ***a*** crisis-relevant ***good***, which ***is*** subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.

2. The notified bodies shall ***make best efforts to*** process all applications for conformity assessment of PPE designated as ***a*** crisis-relevant ***good*** as a matter of priority***, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a***.

▌

4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for PPE designated as crisis-relevant goods in respect ***of*** which they have been notified. ▌

PUBLIC

Article 41c

Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article 19, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market within the territory of the Member State concerned, of a specific PPE which has been designated as ***a*** crisis-relevant good for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated ***in accordance with procedures referred to in that authorisation***.

1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the applicable essential health and safety requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific PPE may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).

The specific PPE subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of a PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ▌ competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market***. The authorisations shall at least set out the following***:

(a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements was successfully demonstrated;

(b) ***any*** specific requirements regarding the traceability of the PPE concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA Regulation***;

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;

(e) measures to be taken ▌ upon expiry of the ***internal market emergency with respect to*** the PPE ***placed on the market***.

▌

▌

5. By way of derogation from Articles 7***, 16*** and 17, PPE, for which an authorisation has been granted in accordance with paragraph 1 shall not ***bear the CE marking and Article 7*** shall not ***apply***.

5a. The market surveillance authorities of ***a*** Member State, ***where*** an authorisation pursuant to ***paragraphs 1, 1a and 1c is valid,*** shall be entitled to take all corrective and restrictive ***actions*** at national level provided for ***under Regulation (EU) 2019/1020 and*** under this Regulation with respect to such PPE.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

▌

8. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned. ▌

PUBLIC

PUBLIC

Article 41e

Presumption of conformity based on standards and common specifications

1. Where PPE ***has*** been designated as ***a*** crisis-relevant ***good***, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications for such PPE to cover the ***applicable*** essential health and safety requirements set out in Annex II in either of the following cases:

   (a) ▌ no reference to harmonised standards covering the relevant essential ▌ requirements set out in Annex II is published in the ***Official Journal of the European Union*** in accordance with Regulation (EU) No 1025/2012***and no such reference is expected to be published within a reasonable period***; ***or***

   (b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation ***of the internal*** Market emergency mode ***in accordance with Article 14 of [the IMERA Regulation],*** significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential health and safety requirements set out in Annex II ▌ and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

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2. The implementing acts referred to in paragraph ***1 shall*** be adopted ▌ in accordance with the examination procedure referred to in Article 44(3) ***and*** they shall ***apply*** until the last day of the period for which the ***internal*** market emergency mode remains active***, unless amended or repealed in accordance with paragraph 5***.

2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 14, PPE which ***is*** in conformity with ***the standards or*** common specifications ***referred to in*** paragraph ***1, or parts thereof,*** shall be presumed to be in conformity with the ***applicable*** essential health and safety requirements set out in Annex II covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

PUBLIC

4. By way of derogation from Article 41a(3), ▌ unless there is sufficient reason to believe that the PPE covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the PPE ***which is in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market shall be deemed compliant with ***the applicable essential health and safety requirements set out in Annex II*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** Regulation ▌ .

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements ▌ set out in Annex II, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

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Article 41g

▌ Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for PPE designated as crisis-relevant goods. ***The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***

2. The market surveillance authorities of the Member States shall ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for ***PPE components*** designated as crisis-relevant goods.'

Article 3

Amendments to Regulation (EU) 2016/426

Regulation (EU) 2016/426 ***is amended as follows***:

(1) In Article 2 the following points are added:

‘ (32) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];

(33) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation];’

(2) The following Chapter Va is inserted after Chapter V:

‘Chapter Va

EMERGENCY PROCEDURES

Article 40a

Application of emergency procedures

1. Articles 40b to 40g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of ***the IMERA*** Regulation.

2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which ***have*** been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

PUBLIC

3. Articles 40b to 40g, except as regards ***the power*** of the Commission ***in Article 40e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

However, Article 40 ▌ c(5) shall apply during the ***internal*** market emergency mode and after its deactivation or expiry.

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to appliances and fittings placed on the market in accordance with Articles 40c to ***40e***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3). ▌

Article 40b

▌ Prioritisation of the conformity assessment of crisis-relevant appliances and fittings

1. This Article shall apply to all appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.

2. The notified bodies shall ***make best efforts to*** process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority***, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a***.

▌

4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect ***of*** which they have been notified. ▌

Article 40c

▌ Derogation from conformity assessment procedures requiring mandatory involvement of a notified ***body***

1. By way of derogation from Article 14, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or ***the*** putting into service within the territory of the Member State concerned, of a specific appliance or fitting which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 14 ▌ have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated ***in accordance with procedures referred to in that authorisation***.

1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex I to this Regulation, the Commission shall without delay adopt an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific appliance or fitting may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).

The specific appliance or fitting subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).

1b. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of an appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the ***an*** appliance or ***a*** fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ▌ competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market***. The authorisations shall at least set out the following***:

   (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;

   (b) ***any*** specific requirements regarding the traceability of the ***appliance or fitting*** concerned;

   (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA Regulation***;

   (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the ***appliance or fitting*** concerned;

   (e) measures to be taken ▌ upon expiry of the ***internal market emergency with respect to*** the appliance or fitting ***placed on the market***.

▌

▌

5. By way of derogation from Articles 6***, 16*** and 17, appliances or fittings, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and Article 6*** shall not ***apply***.

5a. The market surveillance authorities of ***a*** Member State, ***where*** an authorisation pursuant to ***paragraphs 1, 1a and 1c is valid ,*** shall be entitled to take all corrective and restrictive ***actions*** at national level provided for ***under Regulation (EU) 2019/1020 and*** under this Regulation with respect to such appliances or fittings.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

▌

8. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned. ▌

▌

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PUBLIC

Article 40e

Presumption of conformity based on standards and common specifications

1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications for such appliances or fittings to cover the ***applicable*** essential requirements set out in Annex I in either of the following cases:

   (a) ▌ no reference to harmonised standards covering the relevant essential requirements set out in Annex ***II*** is published in the ***Official Journal of the European Union*** in accordance with Regulation (EU) No 1025/2012***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   ▌

   ▌

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** market emergency mode in accordance with Article ***14 of the IMERA*** Regulation ▌ , significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential requirements set out in Annex I ▌ and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

PUBLIC

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

[redacted]

2. The implementing acts referred to in paragraph 1 [redacted] shall be adopted [redacted] in accordance with the examination procedure referred to in Article 42(3) ***and*** they shall apply [redacted] until the last day of the period for which the ***internal*** market emergency mode remains active***, unless amended or repealed in accordance with paragraph 5***. [redacted] .

2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.

PUBLIC

3. Without prejudice to Article 13, appliances or fittings which are in conformity with ***the standards or*** common specifications ***referred to in*** paragraph ***1, or parts thereof,*** shall be presumed to be in conformity with the ***applicable*** essential requirements set out in Annex I covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 40a(3), ▌ unless there is sufficient reason to believe that the appliances or fittings covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the appliances or fittings ***which are in conformity*** with those ***standards or*** common specifications ***and*** which have been placed on the market shall be deemed compliant with ***the applicable essential requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** Regulation ▌ .

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential requirements ▌ set out in Annex I, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

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Article 40g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for ***appliance*** and fittings designated as crisis-relevant goods. ***The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***

2. The market surveillance authorities of the Member States shall ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***an internal*** market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods. ’

PUBLIC

Article 4a

Amendments to Regulation (EU) 2023/988

Regulation (EU) 2023/988 is amended as follows:

(1) In Article 2(1), point (b) is replaced by the following:

‘ (b) Chapter IIa, Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.’

(2) The following chapter is inserted:

‘Chapter IIa

EMERGENCY PROCEDURES

Article 8a

Activation of the emergency procedures, relationship with other provisions of this Regulation and deactivation

1. Articles 8b to 8d shall only apply if the Commission has adopted an implementing act pursuant to Article 14(3) of the IMERA Regulation.

2. Articles 8b to 8d shall only apply to products covered by this Regulation which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Articles 8b to 8d shall apply during the internal market emergency mode activated by a measure adopted in line with Article 14(3) of IMERA Regulation, except with respect to provisions concerning the powers of the Commission.

PUBLIC

Article 8b

Presumption of conformity with the general safety requirement in the context of an internal market emergency

1. ***In addition to the presumption of conformity laid down in Article 7 of this Regulation, where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibility for manufacturers to make use of the relevant European standards already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, it shall be considered, for the purpose of placing products on the market, that the presumption of conformity with the general safety requirement laid down in Article 5 may also be established if the product conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law.***

2. ***In addition to the cases where the presumption of conformity with the general safety requirement laid down in Article 5 applies under paragraph 1 and Article 7(1), Member States shall take all appropriate measures to ensure that, for the purpose of placing or making available of products on the market, their competent authorities consider that the products which comply with the relevant European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012, the relevant international standards developed by a recognised international standardisation body as defined by Article 2(9) of Regulation (EU) 1025/2012, and relevant national standards developed by a national standardisation body as defined by Article 2(10) of Regulation (EU) 1025/2012, are presumed to meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those standards are concerned unless such standards are not adequate in view of the other elements of Articles 6 and 8 of this Regulation.***

3. ***Article 7(3) applies in the presumption of conformity established in accordance with this Article.***



PUBLIC

Article 8d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. ***Member States shall prioritise market surveillance activities for products covered by this Regulation, which have been designated as crisis-relevant goods.***

2. ***The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency.'***

Article 5[10]

Amendments to Regulation (EU) No 305/2011

Regulation (EU) 305/2011 is amended as follows:

(-1) In Article 2 the following points are added:

‘ (29) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];

(30) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(1) The following Chapter VIa is inserted ***after Chapter VI***:

‘Chapter VIa

EMERGENCY PROCEDURES

Article 38a

Application of emergency procedures

1. Articles 38b to 38f ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of ***the IMERA*** Regulation.

2. Articles 38b to 38f shall apply exclusively to construction products, which have been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

[10] In order to ensure the continued application of the emergency provisions also to construction products covered by the new Construction Product Regulation, it is understood that corresponding provisions will also need to be inserted into the new Construction Product Regulation before its final adoption

3. Articles 38b to 38f, except as regards ***the power*** of the Commission ***in Article 38d(5)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

   However, Article 38 ▌ c(5) shall apply during the ***internal*** market emergency mode and after its deactivation or expiry.

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to construction products placed on the market in accordance with Articles 38b to ***38d. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)***.***

▌

▌

Article 38b

Prioritisation of the assessment and verification of constancy of performance of crisis-relevant construction products

1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1).

2. The notified bodies shall ***make best efforts to*** process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority***, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a***.

▌

4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the ***manufacturers, who*** have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods. ▌



PUBLIC

Article 38d

Assessment and declaration of performance based on standards and common specifications

1. Where construction products ▌ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases:

   (a) ▌ no reference to harmonised standards covering the relevant ***essential requirements set out in Annex II*** is published in the ***Official Journal of the European Union*** in accordance with ***Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** market, which led to the activation of the ***internal*** market emergency mode ***in accordance with Article 14 of the IMERA Regulation,*** significantly restrict the possibilities of manufacturers to make use of the harmonised standards ▌ providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of the European Union in accordance with ***Regulation (EU) No 1025/2012***.

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

PUBLIC

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 64(2a) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** market emergency mode remains active***, unless amended or repealed in accordance with paragraph 5***.

2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the ***standards or*** common specifications ***referred to in*** paragraph 1***, or parts thereof***, may be used for assessing and declaring the performance of construction products covered by those ***standards or*** common specifications in relation to their essential characteristics. ***Declaration of performance based on the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 38a(3), ***unless there is sufficient reason to believe that construction products covered by the standards or*** common specifications referred to in paragraph 1 ***present a risk to the health or safety of persons or fail to achieve the declared performance, the declaration of performance of*** construction products which have been placed on the market ***in compliance with the standards or common specifications referred to in paragraph 1 shall remain valid after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the internal market emergency mode in accordance with the IMERA Regulation***.

PUBLIC

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing ***act listing the standard or*** establishing the common specification in question.

Article 38f

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for construction products designated as crisis-relevant goods. ***The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***

2. The market surveillance authorities of the Member States shall ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during an ***internal*** market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated as crisis-relevant goods.'

PUBLIC

(2) In Article 64, the following paragraph 2a is inserted:

'2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.'

Article 5a

Amendments to Regulation (EU) 2023/1230

Regulation (EU) 2023/1230 is amended as follows:

(1) In Article 3 the following points are added:

'***(37) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(38) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation];'

(2) The following Chapter IVa is inserted after Chapter IV:

'Chapter IVa

EMERGENCY PROCEDURES

Article 25a

Application of emergency procedures

1. Articles 25b to 25e of this Regulation shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of the IMERA Regulation.

2. Articles 25b to 25e apply exclusively to machinery and related products, which have been designated as crisis-relevant goods pursuant to Article 14(3) of the IMERA Regulation.

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3. Articles 25b to 25e, except as regards the power of the Commission in Article 25d(5), shall apply only during the internal market emergency mode activated in accordance with Article 14 of the IMERA Regulation.

4. However, Article 25c(4) shall apply during the internal market emergency mode and after its deactivation or expiry.

5. The Commission may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements with respect to machinery and related products placed on the market or put into service in accordance with Articles 25c to 25d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

Article 25b

Prioritisation of the conformity assessment of crisis-relevant machinery and related products

1. This Article shall apply to all types of machinery and related products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 25 requiring mandatory involvement of a notified body.

2. The notified bodies shall make best efforts to process all applications for conformity assessment of machinery and related products designated as crisis-relevant goods as a matter of priority, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 25a.

3. The prioritisation of applications for conformity assessment of machinery and related products pursuant to paragraph 2 shall not give rise to additional disproportionate additional costs for the manufacturers, who have lodged those applications.

4. The notified bodies shall make reasonable efforts to increase their testing capacities for machinery and related products designated as crisis-relevant goods in respect of which they have been notified.

Article 25c

Derogation from conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article 25, any competent national authority may authorise, on a duly justified request from an economic operator, the placing on the market or putting into service within the territory of the Member State concerned, of specific machinery or related products which have been designated as crisis-relevant goods and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 25, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated in accordance with procedures referred to in that authorisation.

2. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the applicable essential requirements laid down in Annex III to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific machinery or the related products may be placed on the market or put into service. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).

The specific machinery or the related products subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market or put into service as a "crisis-relevant goods". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

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1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 48(4).

1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of machinery or the related products subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the machinery or the related products concerned comply with all the applicable essential requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery or the related products may be placed on the market or put into service. The authorisation shall at least set out the following:

(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;

(b) any specific requirements regarding the traceability of the machinery and the related products concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the internal market emergency mode has been activated in accordance with Article 14 of the IMERA Regulation;

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(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the machinery and the related products concerned;

(e) measures to be taken with respect to the machinery or the related products placed on the market upon expiry of the internal market emergency.

4. By way of derogation from Articles 4, 23 and 24, machinery or the related products, for which an authorisation has been granted in accordance with paragraph 1 shall not bear the CE marking and Article 4 shall not apply.

5. The market surveillance authorities of a Member State, where an authorisation pursuant to paragraphs 1, 1a and 1c is valid shall be entitled to take all corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such machinery and the related products.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

6. The use of the authorisation procedure set out in paragraphs 1 to 1c does not affect the application of the relevant conformity assessment procedures laid down in Article 25 on the territory of the Member State concerned.

Article 25d

Presumption of conformity based on standards and common specifications

1. Where machinery or the related products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing common specifications for such machinery or the related products to cover the applicable essential requirements set out in Annex III in either of the following cases:

(a) no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period; or

[redacted]

(b) severe disruptions in the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant applicable essential requirements set out in Annex I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

[redacted]

2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall apply until the last day of the period for which the Single Market emergency mode remains active, unless amended or repealed in accordance with paragraph 5.

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2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert group established under the Regulation.

3. Without prejudice to Article 20, machinery and the related products which are in conformity with the standards or common specifications referred to in paragraph 1, or parts thereof, shall be presumed to be in conformity with the applicable essential requirements set out in Annex III covered by those standards, common specifications or parts thereof. The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the date the internal market emergency mode expires or is deactivated.

4. By way of derogation from Article 25a(3), first subparagraph, unless there is sufficient reason to believe that the machinery and the related products covered by the standards or common specifications referred to in paragraph 1 present a risk to the health or safety of persons, the machinery and the related products which are in conformity with those standards or common specifications and which have been placed on the market or put into service shall be deemed compliant with the applicable essential requirements set out in Annex III to this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the internal market emergency mode in accordance with the IMERA Regulation.

5. When a Member State considers that a standard or common specification referred to in paragraph 1 does not entirely satisfy the applicable essential requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, if appropriate, amend or repeal the implementing act listing the standard or establishing the common specification in question.

Article 25e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. ***The Member States shall prioritise the market surveillance activities for machinery and the related products designated as crisis-relevant goods. The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***

2. ***The market surveillance authorities of the Member States shall ensure that best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for machinery and the related products designated as crisis-relevant goods.'***

Article 6

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from [***OP- please insert the date identical to that of the entry into application of the IMERA Regulation***].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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