

Exceptional rules for products to prevent spread of COVID-19

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Introduction

The rapid spread of COVID-19 pandemic has led to a significant increase in demand for medical devices (MDs) and personal protective equipment (PPE), masks for social use (textile articles) and other products destined to prevent the spread of the disease. As a result, it became clear that there was insufficient supply to meet existing needs during the state of emergency and the subsequent period.

There have already been multiple initiatives to combat the pandemic, particularly by converting production lines to manufacture PPE, MDs and other essential products (eg, biocides).

In view of this and the circumstances of the pandemic, Decree-Law 14-E/2020 of 13 April 2020 was published to establish exceptional and temporary arrangements for the manufacture, import, placement and availability on the market of MDs and PPE. The measures aim to prevent the spread of COVID-19 by setting out the conditions under which it is possible to derogate from or adapt the procedures to assess compliance with the legally imposed health, safety and performance requirements.

Exceptions

These exceptional arrangements apply only to:

- single-use surgical masks for use by healthcare professionals;
- masks for social use, both single-use and reusable;
- respiratory protection half-masks;
- masks with an integrated visor;
- surgical gowns;
- full protection suits;
- hoods;
- caps;
- arm and leg covers;
- protective footwear – overboots;
- protective footwear – overshoes;
- single-use gloves;
- safety eyewear;

- visors; and
- swabs.

Imports

As regards the import of MDs and PPE, it is provided that:

- MDs and PPE necessary to prevent the spread of COVID-19 can be imported even if they bear no CE marking. However, they must be accompanied by certificates or other documents proving that they comply with the rules on health, safety and performance established by other states that are equivalent to those required by EU regulations. The items that can be imported are listed by the National Authority of Medicines and Health Products (INFARMED) in relation to MDs, and by the Economic and Food Safety Authority (ASAE) in relation to PPE; and
- for MDs and PPE without CE markings that do not appear on the list drawn up by INFARMED, the documentation needed to check them must be presented. These items may then be imported only subject to a prior favourable decision by ASAE or INFARMED, as appropriate. At the importer's request, these bodies must issue their decision within four working days. This period may be extended once for an equal period, if it is necessary to consult other bodies.

Manufacturing

MDs and PPE can be manufactured, without CE markings, provided that the manufacturer complies with the health, safety and performance rules indicated for this purpose by INFARMED (for MDs) and ASAE (for PPE). Manufacturers must also submit documentary proof of compliance with the essential health and safety requirements applicable to the products in question.

As regards the requirements for the manufacture, import and marketing of masks for social use (textile articles), Decree-Law 14-E/2020 does not define specific rules, but refers only to the technical requirements that are published by the economic and health authorities.

As a result of this legislation, in April 2020, INFARMED and ASAE published a set of additional rules on procedures for the manufacture, import and marketing of MDs, PPE and social-use masks on their websites. These rules essentially address the equivalence of applicable international technical rules and labelling.

Placing on the market

As to placing and making items available on the market, when the import or manufacture is carried out in accordance with what is set out above, and provided the other requirements for placing products on the market are met:

- the MDs, PPE and masks for social use can be made available on the Portuguese market as long as their health, safety and performance characteristics are guaranteed; and
- respiratory protection half-masks, masks for social use and single-use gloves can also be made available in vending machines.

Final remarks

Lastly, while the original version of Decree-Law 14-E/2020 aimed to facilitate the reorientation of companies' production structures towards the products needed for the pandemic, it made no changes to industrial licensing requirements.

In response to this problem, Decree-Law 36/2020 amended Decree-Law 14-E/2020 by establishing a simplification of procedures for industrial licensing of MDs, PPE, ethyl alcohol and other biocide disinfectant products.

The authorisations resulting from these simplified procedures, which aim to make it easier to place on the market products to prevent the spread of the COVID-19 pandemic, are exceptional in nature and expire 30 days after the repeal of Decree-Law 14-E/2020.

Finally, both Decree-Law 14-E/2020 and the amendment introduced by Decree-Law 36/2020 have retroactive effect as from 13 March 2020 to ensure compatibility with the law containing measures to expedite the production and marketing of products necessary to prevent the spread of COVID-19.

For further information on this topic please contact Eduardo Nogueira Pinto, Eliana Bernardo or Rúben do Carmo Pereira at PLMJ by telephone (+351 213 197 300) or email (eduardo.nogueirapinto@plmj.pt, eliana.bernardo@plmj.pt or ruben.docarmopereira@plmj.pt). PLMJ website can be accessed at www.plmj.com.

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Eduardo Nogueira Pinto Eliana Bernardo Rúben do Carmo Pereira