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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Coronavirus: Exceptional Regime for MDs and PPE

The rapid spread of the new Coronavirus (SARS-CoV-2) and the Covid-19 pandemic have led to a very significant increase in demand for medical devices (MDs) and personal protective equipment (PPE), and there was insufficient supply to meet existing needs during the state of emergency and the period that will immediately follow it.

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There have been multiple initiatives to combat the pandemic, particularly by converting production lines to manufacture of personal protective equipment and essential medical devices. In view of this and the circumstances of the pandemic, Decree-Law 14-E/2020 of 13 April was published to establish exceptional and temporary arrangements for the manufacture, importation, and placement and availability on the market of medical devices (MDs) and personal protective equipment (PPE). The aim of these measures is to prevent the spread of the new Coronavirus 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 that lead to the CE marking being affixed and to the EU declaration of conformity being issued.

These exceptional arrangements only apply to: (i) surgical masks for use by healthcare professionals, both single use and reusable; (ii) surgical masks for social use, both single use and reusable; (iii) respiratory protection half-masks; (iv) masks with integrated visor; (v) surgical gowns; (vi) full protection suits; (vii) hoods; (viii) caps; (ix) arm covers; (x) protective footwear - overboots; (xi) protective footwear - overshoes; (xii) single-use gloves. (xiii) safety eyewear; (xiv) visors; and (xv) swabs.

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

- o The MDs and PPE necessary to prevent the spread of SARS-CoV-2 can be imported even if they do not bear the CE marking. However, they must be accompanied by certificates or other documents proving 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 INFARMED (the Portuguese National Authority for Medicines and Healthcare Products) in relation to MDs, and by ASAE (the Portuguese Authority for Economic and Food Safety) in relation to PPE.

- o For MDs and PPE without CE markings that do not appear on the list drawn up by INFARMED, it is necessary to present the documentation needed to check them. These items may then only be imported subject to a prior favourable decision by ASAE or INFARMED, as appropriate. At the request of the importer, 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.

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MDs and PPE can be manufactured, provided the manufacturer complies with the health, safety and performance rules indicated for this purpose by INFARMED (for DMs) and by ASAE (for PPE). Manufacturers must also submit documentary proof of compliance with the essential health and safety requirements applicable to the products in question.

By 17 April 2020, INFARMED and ASAE must publish the rules referred to above on their websites. These rules may subsequently be updated and revised.

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

- MDs, PPE and masks for social use can be made available to units of the health system and other entities that have adequate sanitary supervision. They can also be made available for sale in pharmacies and authorised points of sale.
- Respiratory protection half-masks, masks for social use, and single-use gloves, can also be freely placed or made available on the market for sale at wholesale and retail establishments and in automatic machines.

Finally, the exceptional arrangements referred to above take effect retroactively as from 13 March 2020. ■

"It is also possible for the Ministers of Health and of the Economy to issue an order allowing surgical masks to be placed or made available on the market, for sale in wholesale and retail establishments, or in vending machines."