



COVID-19

Legal Insights no. 22

Exceptional and temporary regime for manufacture, import, placing and provision, on the national market, of medical devices for human use and for individual protective equipment for the purpose of preventing the infection by the new coronavirus.

The Decree-Law no 14-E/2020, of April 13 establishes an exceptional and temporary regime for the manufacture, import, placing and provision, on the national market, of medical devices for human use (MD) and of individual protective equipment (IPE), for the purpose of preventing the infection by the new coronavirus.

During the outbreak of COVID-19, there may be adaptation or derogation of conformity assessment procedures, legally required for the manufacture, import, national marketing and use of MD and IPE necessary for the prevention of infection of the new coronavirus and listed in this decree, such as surgical masks and gowns, single-use gloves, goggles, swabs, etc.

The abovementioned MD and IPE may be manufactured provided that the manufacturer has complied with the applicable standards and made the relevant supporting documents available.

The MD and IPE without CE marking may be imported provided that they are accompanied by any documents attesting conformity with the applicable rules. The import of MD and IPE with CE marking is subject to a prior favorable decision by INFARMED or ASAE, respectively.

The MD and IPE legally imported under this law, as well as the masks for social use, can be made available (i) to units of the health system and other entities that have adequate health supervision and (ii) for sale in pharmacies and authorized sales areas. Respiratory protection half masks, masks for social use and single-use gloves may also be freely placed or made available on the market, for sale in wholesale and retail establishments and in vending machines.

Also within the scope of this law, it is established that the procedures, decisions and recommendations of the Tax Authority, INFARMED and ASAE, necessary for the manufacture, import, placing and provision on the market of MD and IPE are of urgent and priority nature.

This Decree Law become effective on April 14, 2020 and it is effective as from March 13, 2020.

To access the full text of Decree Law no. 14-E/2020, of April 13, please click on the following link:

<https://dre.pt/web/guest/pesquisa/-/search/131393156/details/maximized>

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