

Informative Note

Import control of PPE and other sanitary material

30th March 2020

As a consequence of the COVID-19 outbreak and the emergency situation our country is going through, the Customs and Special Taxes Department of the Tax Agency published last Friday, March 27th, 2020 a [informative note](#), with the purpose of clarifying certain doubts that could arise when importing personal protection equipment (hereinafter referred to as PPE) and other sanitary material such as gloves, masks, protective suits or goggles. The tariff headings corresponding to such goods are those published by the World Trade Organization, which can be found at the following [link](#).

It is important to point out that the importation of medical products is subject to control by the Spanish Agency for Medicines and Medical Devices. In this sense, the products subject to control are those listed in the Order SCB/278/2019, of March 7 are those that are subject to health controls at the border.

In turn, the performance of the controls is set out in Order SPI/2136/2011, of 19 July, which establishes the modalities of health control at the border by the pharmaceutical inspection and regulates the Computerized System of Pharmaceutical Inspection of Foreign Health (SIFAEX), establishing three types of controls: documentary control, identity control and physical control.

As a general rule, upon arrival of the products subject to review, the corresponding controls will be carried out by the foreign health services, which will validate the corresponding Spanish Pharmaceutical Inspection Document (DOIFE) and will automatically forward it to the control customs office without the need to carry out additional controls, beyond the remaining customs controls that may be relevant.

Given the seriousness of the situation, the Spanish Agency for Medicines and Healthcare Products has relaxed the requirements for the import of certain goods subject to inspection so that, for certain products, other types of authorisations will be accepted in formats other than the DOIFE (special import authorisations, written or e-mail) and in other cases, prior authorisation by the border inspection services will not be required.

Therefore, according to these instructions, prior authorisation will not be required in the following cases:

a) Imports of masks by individuals of up to 2 kgs. with or without CE marking. In these cases, it will be necessary to present, together with the customs import declaration, a declaration from the private individual stating that the masks are for personal use and that they will not be marketed or supplied to third parties.



(b) Imports of masks, gloves or medical clothing by companies for the exclusive use of their employees, with or without CE marking. The Border Inspection Services are replaced by a special authorisation from the Spanish Agency for Medicines and Health Products (in writing or by e-mail) to be attached to the customs declaration.

As for **PPE**, if such equipment is considered a health product, its import will be subject to control by the Border Inspection Services.

In those cases where the import declaration is not accompanied by a DOIFE (Official Spanish Pharmaceutical Inspection Documents), it will automatically be assigned a “yellow circuit” in order to check whether there is any other type of authorisation from the General Department for Pharmacy and Health Products.

It is important to point out that certain masks do not have the condition of a health product, so in these cases it will not be necessary to have prior authorisation from the Spanish Agency for Medicines and Health Products. The list of masks that are not considered to be medical devices can be consulted at the following [link](#). The procedure for dispatch is that provided in the Resolution of 11 July 2014, which contains the instructions for the formalisation of the Single Administrative Document.

We hope the information is useful and of your interest. At Andersen Tax & Legal we have created a multidisciplinary team to attend to all the questions that may arise on this aspect or in relation to the COVID-19.

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