

NEW SYSTEM OF PROCESSING CUSTOMS DESTINATION CERTIFICATES FOR MEDICAL DEVICES WITHOUT A SANITARY REGISTRATION

As of July 2, a Customs Destination Certificate (CDA, in its Spanish acronym) will be required for medical devices¹ that do not have a sanitary registration to be imported into Chile.

The CDA must be requested and obtained by the importer through the Institute of Public Health's (ISP, id.) GICONA 2.0 electronic platform, and will require the payment of an official fee corresponding to the service code 4111027, "Customs Destination Certificate, law 18,164".

Importers of medical devices who are currently registered in the GICONA 2.0 platform may access the CDA-request process by entering the module "Foreign Trade/Imports" (Comercio Exterior/Importación), and selecting the option "Medical Devices without Sanitary Registration" (Dispositivos Médicos sin Registro Obligatorio).

Importers that are not current users of the system will be required to register in the GICONA 2.0 system. This entails identifying as a company or as a natural person, registering a warehouse where the imported medical devices will be stored, and obtaining a password².

Pursuant to Circular 225 of April 6, 2018, issued by the National Customs Service (SNA, id)³, medical devices without a sanitary registration are associated with specific customs codes, which are – in turn – linked to internal ISP codes (currently codes DM-00001 to DM-10072), which are grouped as follows⁴:

Grouped products (customs code)	
30.06	Pharmaceutical goods
34.07	Modelling pastes, waxes or compoun...
33.06	Preparations for oral and dental hygie...
38.22	Diagnostic or laboratory reagents; cert...

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40.14	Hygienic or pharmaceutical articles (i...
87.13	Wheelchairs and other vehicles for dis...
87.14	Spare parts and accessories for vehicl...
90.01	Optical fibers; sheets and plates of pol...
90.11	Optical microscopes, including for ph...
90.18	Medicine, surgery, dental or veterinary...
90.19	Apparatuses for massages, psycholo...
90.21	Orthopedics items and devices for fra...
90.22	X-ray apparatuses using alpha, beta or...
94.02	Furniture for medicine, surgery, odont...
96.19	Sanitary napkins and tampons, diaper...

To submit an online request for a CDA, the importer must upload the invoice, waybill and Quality Certification corresponding to the medical device. In addition, the importation of sterile medical devices will also require the importer to indicate the manufacture and expiration date of the imported batch.

Once a CDA is obtained, it must be submitted to the SNA along with an importation declaration and all other customs documentation required for an importation to be authorized.

Finally, please note that the importation process for medical devices that do have a sanitary registration and that require a Use and Disposal Authorization (AUD) has not been modified and, therefore, will continue to be carried out through the same mechanisms and government services.

1 Further information about this new procedure available [here](#).

2 For further information, see guidelines available [here](#).

3 Available [here](#).

4 Information available at [here](#).

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