Import of Diagnostic Medical Kits shall require Approval

3 Apr 2020

As per the Communiqué on Import of Diagnostic Medical Kits numbered 2020/19 ("**Communiqué**") published in the Official Gazette dated 2 April 2020 and numbered 31087, registration of Release for Free Circulation or Temporary Admission customs declarations for those used on humans of the following goods shall require submission to the customs authorities of physical or electronic letter of conformity to be obtained from the Turkish Medicines and Medical Devices Agency ("**Agency**");

- Goods under the tariff position 3822.00 and described as "supported reactive goods used in laboratories or diagnostics, medicinal reactive goods used in laboratories or diagnostics whether or not supported (except those under 30.02 or 30.06 positions); standard (reference) materials", and
- Goods under the tariff position 3002.15 and described as "immunity products that are dosed or packaged/prepared suitable for retail"

In this regard, provisions of the Communiqué shall not be applied with respect to companies authorized by the Ministry of Health and to declarations registered before 2 April 2020.

With regards to goods within the scope of the Communiqué, the applications to be made by importers as per the Communiqué on Inspection of Import of Medical Devices numbered 2020/16 shall be made after the letter of conformity of Turkish Medicines and Medical Devices Agency is obtained as per the Communiqué.

With the announcement published on the Agency's website on 3 April 2020 regarding the Communiqué, it has been stated that the applications shall be solely made through the Electronic Information Management System of the Agency and that the medical devices subject to the application must be registered to the Product Tracking System.

Please see this link for the full text of the Communiqué (only available in Turkish).