

# Medical device registration and approval in Turkey

With a population that will soon surpass Germany, and the 15<sup>th</sup> largest economy worldwide, Turkey represents a growing opportunity for medical device manufacturers. Although not a member of the European Union, the country is a candidate for EU membership and has adopted many European rules and regulations.

Many people do not realize that Turkey has transposed the EU Medical Devices Directive (MDD) and uses it as a basis for regulating medical devices.

**Therefore, if you have CE marking for your devices, you can capitalize on it to commercialize your products in Turkey. Additionally, if you sell your products to public hospitals and clinics, you'll need to register the device with the Turkish Ministry of Health, in order to be eligible for reimbursement.**

## Getting started in Turkey

Prerequisites for device registration in Turkey include CE marking, specifically evidence of conformity to EU Essential Requirements from either a Notified Body or self-declaration.

Because Turkish regulations emulate the MDD, classification of medical devices are the same as Europe, as are the quality management system requirements.

Turkey does require a local representative in Turkey to register with the Ministry of Health.

Registration requirements also include barcodes that are specific to Turkey and your local representative, or, you may provide barcodes that you use for other markets like the US or Europe.

## How we support medical device registration in Turkey

With offices in Istanbul, Emergo has the resources and expertise to register your devices with the Turkish Ministry of Health (Sağlık Bakanlığı)

Our services include:

- Preparation of all application documents, including proof of CE Marking and conformity to EU Essential Requirements
- Coordination of documentation translation into Turkish
- Submission of all registration documents through the Turkish Pharmaceutical and Medical Device National Databank (TITUBB)
- Independent authorized representation as your regulatory liaison in Turkey

- Independent representation as your commercial representative with the MoH
- Support with generating required barcodes for your products
- Guidance on the appropriate reimbursement code selection
- Managing Turkish customs audits of your device, if necessary

If your legal department wants to do themselves they must study the following websites, legislations, regulations

<https://titubb.titck.gov.tr/>

<http://www.sgk.gov.tr/>