



The Legal Framework for the Production of Medical Devices in Tunisia

DIEM & PARTNER Rechtsanwälte

Due to a highly qualified workforce, an advanced degree of market openness and the preferential economic relations with the European Union, Tunisia is an attractive location for the production of medical devices. After the adoption of a new Constitution in January 2014 and the end of the political deadlock the country promises to be one of the most interesting places to do business in the whole MENA-region.



But does this also apply for the particular field of medical technology? Following we take a look at the question which legal conditions are applicable for the production of medical devices in Tunisia by foreign investors.

Long-standing know-how for the production of medical devices

The bulk of the production of medical devices in Tunisia concerns products that are relatively simple, but nonetheless of high quality. For example, Tunisian companies have a long and thorough experience in manufacturing fittings for hospitals and medical practices, wheelchairs, orthopedic products, and medical consumables. In 2010, Tunisia exported medical devices worth €84 million. But also within Tunisia, the demand for medical devices is growing, because Tunisia is a destination for health and wellness tourism. Tourists that come to Tunisia for medical treatment are mainly from neighboring Algeria and Libya, where the know-how and the capacities for state-of-the-art treatment are missing, especially in the fields of cardiology and oncology, but also in the fields of esthetic surgery, ophthalmology, and dentistry. Yet, not only the private health sector is thriving. Also the modernization of the 176 public hospitals is on top of the reform agenda.

The new constitution – a guarantor for a democratic and investor-friendly environment

On January 27, 2014 Tunisia's Constituent Assembly adopted a new constitution with a sweeping majority of 200 of 216 votes.

According to many political analysts, the new constitution will send out a message of stability after a long period of political deadlock. It is regarded as one of the most progressive in the region, guaranteeing equal rights for men and women and full freedom of faith. In economic terms, the new constitution demands that the state tackles corruption and provides that intellectual property rights are guaranteed.

General information on the legal framework for investors in Tunisia

Applicability of the Investment Promotion Code on the production of medical technology in Tunisia

Foreign investment in Tunisia is governed by the Investment Promotion Code (Code d'incitations aux investissements, Law no. 93-120 of December 27, 1993), which covers investment in all major sectors of economic activity, including medical technology.

The Tunisian Investment Promotion Code and its subsequent amendments provide for a wide range of incentives for foreign investors, including tax relief on reinvested revenues and profits, limitations on the value-added tax on many imported capital goods, and optional depreciation schedules for production equipment.

The Tunisian Investment Code distinguishes between offshore and onshore activities.

The offshore regime refers to "totally exporting companies" ("entreprises totalement exportatrices"), meaning that foreign capital accounts for at least 66% of equity and at least 70% of production destined for the export market. Totally exporting companies benefit from total tax exemption during the first 10 years and from a reduced tax rate of 10% thereafter.

A reform of the Investment Promotion Code is imminent, and further incentives may be put in place to attract foreign investment in Tunisia.

In the spring of 2011, the Tunisian Investment Promotion Agency (FIPA) announced a series of new incentives to draw investment to structurally weak areas in the interior regions of the country. Every enterprise established in these regional development zones is entitled to very important fiscal, financial and social incentives.

Investment in manufacturing industries requires only a simple declaration of intent to invest. In other sectors, it may be necessary to obtain a series of authorizations by the government.

Foreign investors can transfer returns on investments at any time and without prior authorization. This applies to both principal and capital in the form of dividends or interest.

Settlement of legal disputes

Although Tunisia is not notorious for investment disputes or discrimination of foreign investors in court proceedings, it is highly recommendable that contracts for trade and investment projects should always contain an arbitration clause. Tunisia is a signatory to the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, so that the enforcement in Tunisia of decisions rendered by international arbitral tribunals is not problematic. The German-French Chamber of Industry and Commerce in Paris (CFACI) has its own arbitration center that is also experienced in administering arbitration cases between German investors and their business partners from the Maghreb countries. Moreover, due to the CFACI's administrative office in Paris and its perfect bilingualism an arbitration clause providing for the jurisdiction of the CFACI is an interesting alternative to more prestigious arbi-



tration institutions that is in most cases acceptable for the Tunisian business partner.

Protection of property rights

An issue of particular importance for investments in the field of medical technology is the protection of property rights. Tunisia is a member of the World Intellectual Property Organization (WIPO) and is signatory to the United Nations Agreement on the Protection of Patents and Trademarks. The body responsible in Tunisia for patents and trademarks is the National Institute for Standardization and Industrial Property (Institut National de la Normalisation et de la Propriété Industrielle, INNOPRI). It is advisable to register foreign patents and trademarks with INNOPRI, since Tunisia's patent and trademark laws are designed to protect only owners duly registered in Tunisia.

Although the concept and application of intellectual property protection is still in the process of development, the Tunisian government has increased its enforcement efforts in this area.



Specific regulations in the field of medical technology

According to the decree no. 94-492, which defines the activities covered by the Investment Promotion Code, the production of medical devices falls under the scope of investments fostered by the preferential regime installed by the Investment Promotion Code.

However, with respect to certain heavy medical equipment (e.g. magnetic resonance tomographs), special authorizations are required by the Ministry of Public Health.

Furthermore, the Tunisian administration distinguishes between sterile and non-sterile consumable items on the one hand and medical devices on the other hand. Whereas no special authorization is needed for the latter category (with the exception of certain heavy medical equipments), medical consumable items (e.g. injections) require an authorization by the Ministry of Public Health. The authorization for the production of such consumables is only given if international norms are fulfilled.

By production of goods the Tunisian legislator understands the realization of at least 40% of the manufacturing process in Tunisia. This means that the mere assembly of components cannot be regarded as "manufacturing industries" in the sense of title 1, article 1 of the Investment Promotion Code.

Résumé

Although there is still a long way to go until ideal investment conditions are realized (if such a thing exists at all), the legal framework for the production of medical technology in Tunisia is very attractive. This is due to the openness of the market and the significant incentives provided for by the Investment Promotion Code. Especially when the production of medical devices in Tunisia is destined for export, there are numerous benefits for foreign investors. Due to the highly skilled workforce in Tunisia, the still modest labor costs, and the geographical location of Tunisia between Europe and the rest of Africa, there are also many economic arguments in favor of establishing a production site for medical devices in Tunisia.

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Dr. Daniel Sven Smyrek
Rechtsanwalt and Avocat à la Cour
(attorney admitted in Germany and France)
DIEM & PARTNER Rechtsanwälte,
Stuttgart