European Commission

Managing your IP in the Medical Device Sector

The market for medical devices is vast and highly segmented, covering a large number of different products, such as respirators, syringes, infusion pumps or heart rate monitors.

13,833 patent applications were filed in **2019** with the **European Patent Office (EPO)** in the field of medical technology – **7.6 %** of the total number of applications.

Source: EPO (2020)

DID YOU KNOW that medical instruments are the **world's 20th most traded product**?

Source: OEC (2020)

PATENTS

A patent is an exclusive right granted for an invention. Be aware that, as in Europe, most Latin American countries provide a grace period prior to the filing of the application, during which certain disclosures of the invention will not be taken into account when evaluating the novelty and inventiveness of the application.

Note that the grace period is more extensive in Latin America (it typically lasts for 1 year, as opposed to 6 months in Europe) and covers a wider range of disclosures. While most European IP offices will only disregard previous disclosures made during international exhibitions or due to an evident abuse in relation to the applicant, Latin American IP offices such as INPI in Brazil will not consider the prejudicial disclosures that are made by the inventor, regardless of the context of said disclosure.

UTILITY MODELS

Given the short lifecycle of many medical devices, utility models can be a suitable option for protecting extra functionality features, as they are quicker to obtain than patents. Aimed at protecting minor inventions, such as adaptations or improvements of existing products, this type of protection is frequently used in Argentina, Brazil, Colombia and Mexico.

INDUSTRIAL DESIGNS

Design protection requires that the features sought to be protected must be new and/or original, as well as of a purely decorative nature: features with a technical purpose cannot be protected as a design.

COPYRIGHT

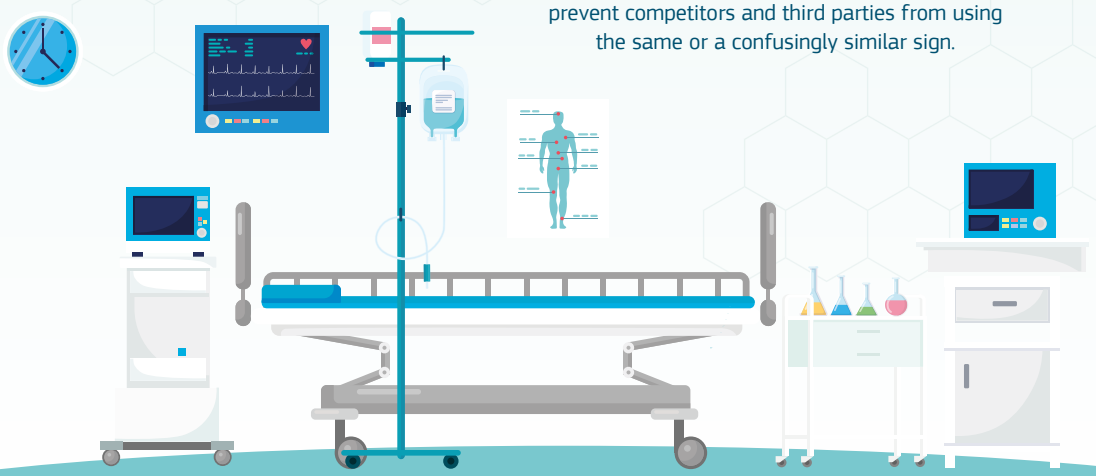
The rise in IT-based innovations has had an impact on the field of medical devices since they rely on the functioning of 'medical software'. Copyright registration is not required but highly recommended in the region.

TRADE MARKS

Any letters, words, phrases, logos, symbols, etc. used in commerce to identify the source of goods may be registered as a trade mark. A registered trade mark is an effective tool for the owner to prevent competitors and third parties from using the same or a confusingly similar sign.

TRADE SECRETS

In order to safely exchange confidential information regarding intellectual property with Latin American partners, non-disclosure agreements (NDAs), licences, assignments and R&D contracts are key tools for EU SMEs looking for opportunities to develop, use or exploit new products in this region.



Managing your IP in the Medical Device Sector

TOP 3 exporters and importers of medical instruments in the region of Latin America

(% of global market share in 2018):

Source: OEC (2020)

EXPORTS

7.61 %	Mexico
2.3 %	Costa Rica
0.46 %	Dominican Republic

IMPORTS

1.25 %	Brazil
1.21 %	Mexico
0.38 %	Colombia

Data on importation of medical device in Latin America during 2019:

Source: Global Health Intelligence (2020)

Mexico

- 80% increase in computed tomography machines and parts
- 75% increase in heart valves and ultrasound machines

Argentina

- 9.7% increase in MRI machines & parts

Colombia

- 38% increase in CT scanners & parts

Chile

- 80% increase in CT scanners & parts

WATCH OUT!

1. In order to ensure the safety and effectiveness of the products, medical devices must meet certain specific commercial and health requirements. Get informed, obtain the necessary approval and register the products you intend to import or manufacture with the competent institutions:

- **Argentina**
  Medical Technology Food and Drug Administration (ANMAT)
- **Brazil**
  The National Health Surveillance Office (ANVISA)
- **Colombia**
  The Ministry of Health and Social Protection (INVIMA)
- **Mexico**
  The Medicines Regulatory Agency (COFEPRIS)

2. The concept of medical devices may differ from one country to another: The dividing line between medical devices and medical products can be very thin and the difference depends on the national legislation. However, it is an important legal distinction, as it entails different regulatory requirements (e.g. clinical trial evidence, approvals...).

Statistics by international IP applications (2019)

Source: WIPO (2020)

PATENTS

Medical technology represents the 4th field of technology in number of **Patent Cooperation Treaty (PCT) applications.**

TRADE MARKS

Class 10, which **includes surgical, medical, dental and veterinary apparatus and instruments,** represents a 22% share of the total amount of **Madrid applications.**

INDUSTRIAL DESIGNS

Class 24, which includes **medical and laboratory equipment,** represents a 2% share of the total amount of **Hague applications.**

Do not miss the glossary of IP key terms and concepts available on our Library!

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