

THE MAIN ACTIVITIES OF MEDICAL DEVICES' DEPARTMENT WITHIN MEDICINES AND MEDICAL DEVICES' AGENCY

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According with the Law nr.92 from 26.04.2012, The MMDA was created, as an administrative authority subordinated to Ministry of Health. The MMDA's activity is regulated by Republic of Moldova's Constitution, decrees of the Republic of Moldova's president, ordinances, decisions and Government's orders, other regulatory documents, international agreements which Moldova joined and the MMDA's Regulation.

The main directions of MMDA' activities in Medical Devices' field:

- Authorization (the expertise, the approval, and the registration) of Medical Devices (MD) with their placement on market;
- Surveillance of MD 's quality;
- Monitoring and coordination of the supply's process with MD at national level;
- Reglamentation and application of harmonised international standarts in MD's field;
- Monitoring the MD's incidents placed on the market through the vigilance's system ;
- Building of the State Registry of MD;
- Building of a national database of MD which include data of the engineers who are responsible for their maintenance;

Department's Tasks

- Monitoring the supply of medical devices, particularly for public medical institutions involved in the mandatory health insurance system and the implementation of national programs;
- Argumentation and the promotion of the proposals concerning improving the health care system in matter of supply with medical devices of all medical institutions;
- Regulation of creating medical devices' market by authorizing the import of medical devices
- Providing with information the health system in medicine and medical devices' field;
- Participates to the development of standardization's programs in the field of medical devices in order to harmonize the local standards with the European directives for medical devices;
- Monitoring the compliency to european and international harmonized standarts through the revision of local regulations and normatives in field of MD;
- Application and connection to the international surveillance and vigilance system of medical devices.