

Registration of medical devices and medical device manufacturers

Health Minister's Order no. 1689/2005 ("the Order") prescribes how and on what terms medical devices and entities engaged in the making of medical devices ("the manufacturers") are registered.

For the purposes of the Order, medical devices include:

- Active medical device implants;
- Medical devices for in vitro diagnosis.

The Order regulates the procedure leading to registration with the Health Ministry (the documents to be submitted, the fees due, the authorities responsible for issuing the registration certificate, the validity of the registration certificate, etc.) in respect of:

- Medical devices bearing the EC marking, put on the Romanian market by health-care entities acting as manufacturers or importers;
- Medical devices not bearing the EC marking, which are registered by the manufacturer or the manufacturer's authorised representative;
- Romanian manufacturers of medical devices.

The procedure whereby the importation of medical devices is regulated separately by the Order.

In charge of implementing the Order is the General Pharmaceutical, Pharmacy Inspection and Medical Appliances Division ("DGIFAM"), the Technical Office for Medical Devices ("OTDM"), as well as the recognized certification bodies.

ODTM will be established through the reorganisation of the Medical Appliances Checking and Maintenance Station ("SVIAM"). Pending establishment of ODTM, its powers and duties are to be exercised by SVIAM.

The Order took effect on 1 January 2005.

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Licences for the right to use the medical devices, the registration certificates and the operating licences for medical device manufacturing activities issued before the effective date of the Order remain valid until after their expiration dates.

Health Minister's Order no. 846/2004 approving the transfer of powers from the authority in charge of medical devices reporting to the Health Ministry to SVIAM was repealed on the effective date of the Order.

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