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# NEW REGISTRATION REQUIREMENTS FOR MEDICAL DEVICES IN POLAND

The **new Polish Act of 20 May 2010 on medical devices** published on the 18th September 2010 (Official Journal of Law No. 107, item 679) will fully enter into force in May 2011 with the application of the last provisions regarding the European Databank EUDAMED.
Let's have a look on the main changes regarding registration/notification of medical devices in Poland.

The registration procedures as well as the registration forms have changed. Currently only entities with the place of business in Poland are obligated to make notifications of medical devices (art. 58 of the above mentioned act).

This means that a US manufacturer or its European authorized representative (EAR) which is not located in Poland cannot register the devices any longer. Instead of that this is the distributor or importer with the registered office in Poland which is obligated to perform a registration.

The article 64 gives the explanation why the manufacturer or the EAR not located in Poland cannot perform anymore the notification : EUDAMED.
A European Commission decision adopted last April 2010 require all European Union countries to use the European databank for medical devices by May 2011. The notification data shall be enter into EUDAMED by the competent authority where is located the Manufacturer or the EAR. If the EAR is located in France such as MediMark Europe, this is only AFSSAPS, the French NCA who can enter the device data into EUDAMED.
In conclusion, although the Polish NCA will have access to these data, they want to keep an eye on the products used in their territory and has included the article 58.3 in their new law.

Another change is that all class medical devices are covered by this obligation. On the other hand distributors and importers are obligated to make only a notification as described in art. 60. The full report on medical device as described in art. 59 is only mandatory for Polish manufacturers and Polish authorized representatives.

The notification must be made by distributor or importer within 7 days after entering the first device into the territory of Poland.
It is important to note that according to the definition of a "distributor" (art. 2.1 point 12 in combination with point 29) this term don't only mean an assigned company which is buying a medical devices from the manufacturer and after that is selling them on the territory of Poland, for example to the hospitals. A "distributor" can also be a hospital by itself in case when it's buying a device directly from a manufacturer. In such case the hospital will be responsible for making a notification of a medical device which is put into service in the territory of Poland. Moreover if there is more than one distributor of the same device, each one is responsible for making the notification independently.

Concerning the art. 17 the importer of the device shall provide the copies of declaration of conformity as well as the certificates (if applicable) during every customs clearance (which means with every shipment of the device).

The labelling and IFU as written in the art. 14 is allowed to be in English (except the information intended to the patient) but MD manufacturers have to take into account that the professional user can ask you to provide the IFU in Polish anyway.

The fees for the notifications have also changed. Currently the fee for the full report on medical device costs 300 PLN (115 US$) and for the notification it is 30 PLN (11.5 US $) per device.

The address of he Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is: Ząbkowska 41 ; 03-736 Warszawa POLAND
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