

New Italian Device Registration Requirements

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A medical device manufacturer located outside Europe was informed by an Italian distributor that the European Authorised Representative must designate the distributor as the authorised entity when registering the manufacturer's devices in Italy in a new online data bank. This is incorrect. This article discusses the new requirements for registering medical devices in Italy, together with the steps in the registration process and common problems encountered.

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New registration system

Two Italian Decrees issued on 20 February 2007 and 20 March 2007 by the Italian Ministry of Health (MOH) introduced a new system for registering medical devices in Italy. These Decrees can be found on the MOH website in the Italian language only.¹ The first Decree, Decreto del Ministero della Salute, 20 febbraio 2007, describes the new registration requirements. The second, Decreto del Ministero della Salute, 20 marzo 2007, specifies the criteria for registering more than one medical device as a "unico dispositivo" or single device.

According to the MOH, the new system is intended to improve the previous medical device registration process and enhance device traceability. This is to be accomplished by assigning a registration number to each device, thereby facilitating the MOH's market surveillance and vigilance activities.

The MOH states that the new data bank will be used to generate a complete list of devices (called a "Repertorio") that are sold to the Italian national health service, the Servizio Sanitario Nazionale (SSN). If a company wishes to sell its products to the SSN, the inclusion of the device in the "Repertorio" will require a fee of €100 for each device or group of devices that share the same registration. If a company does not wish to sell its products to the SSN, the fee is not required, but the new registration process is still mandatory. Registration without paying the fee will allow sales to private Italian institutions.

The new registration requirements apply to medical devices, complete systems and kits such as those used in surgical suites, and active implantable medical devices. They do not yet cover custom made devices, in vitro diagnostic medical devices or devices intended for clinical investigations. It is unclear when these devices will require registration under the new procedures.

A phased introduction

The requirements for the new registration procedures are being introduced in two phases. Any medical device introduced onto the Italian market after 1 May 2007 must be registered using the new procedures and registration must be completed before the device(s) can be sold in Italy. Companies with devices that were registered with the Italian MOH before 1 May 2007 under the previous registration system have until 31 December 2008 to comply with the new requirements, including payment of the "Repertorio" fee.

Given the complexity of the process and the periodic problems of accessing the required database, companies with large inventories of medical devices that will need to be registered before 31 December 2008 should begin the registration process now. As discussed in this article, the process of complying with the new Italian registration requirements is far from straightforward. Thus, companies will need to devote considerable time to the registration process to ensure that the new requirements are met. If companies are found not to have registered any devices that are being sold in Italy, legal sanctions may be applied to the manufacturer and/or distributor.

Access to the database

The process that must be followed to gain access to the registration database depends on whether or not the registration will be conducted by companies located inside or outside Italy.

Italian companies. The registration process for Italian companies is described on the MOH website.² These companies can access the database through the online service "Dispositivi medici" (medical devices), which is found on the "portale per le imprese" (industry web portal) available on the web-



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site: www.impresa.gov.it. To access this service, the company must be in possession of a “smart card,” which allows a user to digitally sign or authenticate the data that has been entered into the database. The legal representative of the company is authorised to use the “Dispositivi medici” online service and is also able to subdelegate one or more persons to act on behalf of the company. To be delegated for this responsibility, each individual must be in possession of his or her own smart card. Links to Italian companies that provide smart cards that can be used in Italy are on the Italian MOH’s website.

NonItalian companies. When companies are located outside Italy, it is necessary to request a user name and password from the Italian MOH for each manufacturer whose devices must be registered. The procedures for obtaining a user name and password are described on the MOH website.³ This information and a User Manual⁴ that can be downloaded from the site are in English. However, the medical device database is in the Italian language only.

The use of the Italian language in the Italian database is not the only problem that foreign companies face when seeking to register their medical devices in Italy under the new system. Once these companies have obtained a user name and password from the MOH and manage to enter the data into the database, they discover that without a smart card, it is impossible to complete the process. Unfortunately, it is difficult to determine how to obtain a smart card if the request is being made from a company located outside Italy. Repeated attempts to obtain this information from the MOH and Italian companies that supply these cards have failed.

Foreign companies face yet another problem. The registration process can be completed by the manufacturer or other individuals that the manufacturer may designate. However, the user name and password obtained from the MOH can only be used to register the devices of one manufacturer. Companies wishing to register medical devices of more than one manufacturer must apply to the MOH for a user name and password for each manufacturer. Italian companies are not limited in this manner.

Database User Manual

The information required for the registration of medical devices into the database is specified in Annex 1 of the Italian Decree of 20 February 2007. There are approximately 50 questions that must be answered for each device or family of devices; however, some questions are optional and others require answers for only certain types or classification of devices. Certain documents must be provided electronically and uploaded to the MOH website.

The criteria for determining how many devices can be included in a single registration are specified in the Italian Decree of 20 March 2007 and cannot be determined from the information provided in the User Manual for the medical device data bank. The Decree indicates that for devices to be included within a single registration, all the products must be included within the same design and development plan; be made of the same material(s), although it is possible to have

different dimensions and shapes; be included within the same essential requirements evaluation; be included within the same risk management file; have the same intended use and principle of operation; be of the same risk classification; and share the same clinical data.

All the data fields for the required information are described in the User Manual. For example, a section of the manual titled, Documentazione (Documentation) is found on page 43 of revision 1.2 of the Manual. This section lists the documentation that should be provided, which can be in the form of attached files or links to files on the Internet. The documents requested are

- Etichetta (Label): upload required for all devices
- Istruzioni per l’uso (Instructions for use): upload required for devices of Classes of IIb and III, optional for Classes I and II
- Immagine del DM (Images of the medical device): optional
- Scheda tecnica del DM (“Technical profile” of the medical device): upload, Internet link/e-mail address required for all devices
- Bibliografia Scientifica (Scientific literature supporting the clinical evidence of performance and safety): upload, Internet link or e-mail address required for all devices.

The field “Scheda Tecnica” is not equivalent to Technical File or Technical Documentation. The User Manual specifies the various types of information that the MOH considers to be part of the “Scheda Tecnica” and it is similar to the type of information that was required under the previous Italian device registration process. However, the elements of the Scheda Tecnica may be more difficult to locate and select, because they are not clearly related to the generally understood parts of a Technical File. These elements include a schematic of the functioning or use of the device (Schema di funzionamento/utilizzo), information on its maintenance, storage, and other information and terminology not generally recognised in the medical device sector outside Italy. Unfortunately, this can lead to various interpretations of what the MOH requires.

Other information required by the data bank includes the global medical device nomenclature (GMDN) code for the device. This can cause problems for manufacturers who have not yet decided to join this voluntary coding system. A recent change to the data bank has also led to the additional requirement to upload copies of Notified Body certificates confirming compliance with one or more of the Annexes of the Directives.

Final steps in the registration process

Once all the required data have been entered, it must be “validated” by means of the electronic signature held on the smart card. The data bank then shows that the entry is at the “Validato” stage. The MOH reviews the detail of every single entry and this can take up to 30 days. Should the reviewer find a problem, an e-mail in the Italian language will be sent to the person making the entry with a request for amendments to be made. Once the MOH is satisfied that the registration has been made correctly, it changes the status of the entry from “V” for “Validato” to “P” for “Publicato.” This

means that the information has been “published” on the data bank and any person authorised to obtain device information from the data bank can see the product details.

This is not the end of the process. For the SSN to be able to purchase the device, details of payment of the “Repertorio” fee must be entered in a separate page in the data bank. Once this has been successfully completed, the unique device registration number held in the data bank acquires a “/R” suffix, to indicate to all that the Repertorio fee has been paid and therefore that the device is available for purchase by the SSN.

An uncertain future

Unfortunately, the Italian registration process appears to be the most complex in Europe and has caused much confusion and frustration among manufacturers, distributors and authorised representatives. Despite this aspect of the data bank, it is active and accepting device registrations, and there are approximately 15 000 at the time of writing.

The Directive revising the Medical Device and the Active Implantable Medical Device Directives, 2007/47/EC, reinforces the European Parliament’s desire for a central European database (EUDAMED) to be set up, and has instructed the European Commission to achieve a fully functional system “no later than 5 September 2012.” If the original objective of the EUDAMED database is met, there may be no further justification for individual member states to introduce or maintain their own specific registration schemes.

References

1. www.ministerosalute.it/dispositivi/dispomed.jsp. Click on “archivio” (file) under the heading “Normativa” (regulations). The two Decrees are listed as “Decreto del Ministero della Salute 20 febbraio 2007” and “Decreto del Ministero della Salute 20 marzo 2007.”
2. Registration process for Italian companies: www.ministerosalute.it/dispositivi/paginainterna.jsp?id=392&menu=registrazione
3. To obtain a user name and password: www.ministerosalute.it/dispositivi/paginainterna.jsp?id=395&menu=registrazione
4. Link to the User Manual in English: www.ministerosalute.it/imgs/C_17_pagineAree_395_listaFile_itemName_2_file.pdf [mdt](#)

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