Changes within the new EU directive

(2007/47/EC) on CE marking of Medical Devices

Substantial changes have been introduced on active implantable medical devices as well as on all other medical devices by the new EU directive 2007/47/EC, into force from October 11th 2007. According to the new directive, all Member States "shall apply [the transposition measures] from March 21st 2010". The consolidated Directive has become mandatory as of March 21st 2010, without any period of transition. Thus, in absence of any transitional provisions, medical devices placed on the market or put into service after March 21st, 2010 must meet the requirements of the revised directive. The introduction of these standards at national level emphasizes the need for companies operating within the Community to acquire adequate information to avoid mistakes on the interpretation of the regulations. The novelties introduced by the directive will have implications for manufacturers, Notified Bodies and national authorities.

Although the previous Medical Devices Directive 93/42EEC has not been radically changed, a series of clarifications and innovations have been added to improve the interpretation of procedures for the evaluation of products across Europe. The changes concern, among others, the essential requirements which medical devices must satisfy in order to be legally placed on the market, the procedures to evaluate the conformity of the devices as well as their classification. Following are some of the changes which may have an impact on manufactures and/or final users.

Changes introduced by the 2007/47/EC

• INTENDED USER: The duty to specify the intended user makes it compulsory for manufacturers of tailored medical devices to prepare clear and detailed instructions for their devices considering the end users skills and knowledge.
This requirement is particularly important for devices intended for non-professional use.

• CLINICAL EVALUATION: The new directive emphasizes the need to provide clinical evidence for all devices. All devices are now in need of such data, including devices for Class I. This is undoubtedly the most important innovation of the entire Directive. Additionally, this imposes more stringent requirements for what constitutes "clinical trial" and calls for a stronger attention from the authorities. Annex X on clinical evaluations has been changed. Consequently, manufacturers must now analyze and review the clinical part during the planning stage to identify any problem that needs further investigation. Such control will be inserted in the document risk analysis at the design stage but also after the commercialization of the product in order to keep updated to the state of art all the technical data of the medical device. In fact, for a better demonstration on the compliance of the medical device, manufacturers are obliged to implement a procedure to review the production of the device even after its commercialization, with the duty to report to the authorities any accidents or withdrawal from the market. Clinical data may come from the following sources, to mention a few: a) clinical investigations carried out for the specific device b) clinical trials or other studies published in scientific literature relating to similar devices, where the equivalence of products must also be demonstrated c) Reports published on other clinical experiences related to the device or similar devices, where the equivalence of devises must be demonstrated.

• STAND ALONE SOFTWARE: Directive 2007/47/EC specifies that the software itself, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device must be considered a medical device. So the software must be validated according to the state of art, taking into account the principles of life cycle development, risk management, validation and verification. Harmonized standard EN IEC 62304:2006 "Medical device software - the processes of software life cycle" may be used to comply with new regulations. Moreover, software considered a medical device must be classified according to the classification rules set out in 93/42. Note that the stand-alone software is considered an active medical device (Annex IX, rule 1.4). For example, software packages that run on PC or Smartphone, which allow you to make diagnosis (telemedicine application) or involved in treatment plan (e.g. the simulation of surgical implants) are now considered active medical diagnosis or treatment. Therefore, as a stand-alone software it must be CE marked to indicate its compliance with the provisions of the Directive to enable them to move freely in the Community and be operated according to their destination.

• **ERGONOMIC DESIGN:** To ensure patient safety, ergonomic design is now considered an essential requirement of the medical device. The ergonomics of medical products is becoming the focal point of the development process. The harmonized standards EN 60601-1-6 and EN 62366:2008 can be used to demonstrate compliance with this requirement.

• **SINGLE USE:** Particular care must be taken to ensure that the reprocessing of medical devices does not endanger the health and safety of patients. Thus, for single-use devices, manufacturers must now provide all the information on known characteristics and technical factors that could pose a risk if the device were to be reused.

• **CONFORMITY ASSESSMENT:** Manufacturers of sterile medical devices and measurement can now enjoy greater flexibility in selecting the route to demonstrate compliance of their device. In fact, it has been introduced, specifically for them, the possibility of adopting a complete system of quality assurance in accordance with Annex II of Dir 93/42. This will be very useful for those manufacturers who are already certified under this Annex or for those that may also want to be included into this certification scheme accessories to their medical device that until recently needed to follow a different approach.

• **E-LABELLING:** The labelling of medical devices in the EU poses a challenge for producers that should provide instructions for use (IFU) in different languages. Currently, most IFU are provided in paper format, which can be very long. The term "e-label" refers to the possibility of using innovative means to provide IFU electronically. The new Directive 2007/47/EC gives to the manufacturer the possibility to provide information related to the medical device by other means. It could potentially allow to provide IFU in a CD or other electronic means, eliminating the various versions of paper now required.

• **DECLARATIONS OF CONFORMITY:** Manufacturers of medical devices are required to declare compliance with the directive of their product in a Declaration of Conformity. Declarations of conformity issued from March 21, 2010 are automatically referred to the revised Directive. From such date, manufacturers must be able to demonstrate compliance with all requirements of the revised Directive which apply to their product. If manufacturers have placed on the market or put into service products to meet the new requirements before March 21, 2010, they must have already declared that their Declaration of Conformity refers to Directive 93/42/EEC as amended by Directive 2007/47/EC. Otherwise, as in the case of declarations of conformity issued before October 10, 2007 (publication date of the amendment 2007/47), the statement should have been reprinted. When a notified body is involved in conformity assessment (e.g. peripheral class II or higher) it has to follow a similar procedure. A Practical Guide to EU-wide standards for the issuance of the new Declaration of Conformity can be found in the following document from the Commission on Implementation of Directive 2007/47/EC amending Directives 90/385/EEC, 93/42/EEC and 98/8/EC of June 5, 2009.

The need to implement Directive 2007/47/EEC at national level within the European Community has enabled the EU Member States to introduce, with some limitations, further elements necessary to adapt the EU legislation to the specific national contexts, thus introducing different regulations in each country. It is therefore important that all companies intending to commercialize their products in the EU become aware of all the elements introduced in each single country within the community.

For further information and legal consultancy on CE certification:

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Implementation of the new EU Directive (2007/47/EC) in the Italian Legislation

The need to transpose Directive 2007/47/EEC (mandatory as of March 21st 2010) at national level within the European Community has enabled EU Member States to introduce, with some limitations, further elements to the specific national contexts. The introduction of such regulations underlines the necessity for medical companies operating within the Community to acquire adequate information to avoid incurring risks.
This article will focus on the implementation of such directive in Italy, through the Legislative Decree 25 January 2010, no. 37, published in the Official Gazette no. 60 dated 13 March 2010. Given the rapid technical changes occurred in the design, production, use and safety of medical devices, this Decree is intended to make Italian legislation on medical devices more coherent.

As well as transposing the technical aspects of the new Directive, the Italian legislation has undergone adjustments on "supervision of accidents", "clinical trials", "publicity" and "penalty system".

In particular, rules governing the supervision of accidents present significant innovations: all withdrawals of medical devices from the market imposed by the Ministry of Health are under the responsibility and at the expenses of the manufacturer if the manufacturer has wrongly applied the technical regulations of the EU Directives or even if he has applied them correctly but they are not specific and complete for his type of production.

If the manufacturer fails to observe the obligation of withdrawal, it is considered a criminal offense. This subject is governed by Article 9 that replaced Article 10. The different types of accidents to be reported by health professionals (paragraphs 2 and 3) and manufacturer (paragraph 7) are included in the 1st paragraph of this article, while the methods of communication are currently defined in the Ministerial Decree 15.11.2005.

Lastly, the manufacturer must provide a method for assessing the experience acquired on his devices during commercialization (post-marketing follow-up, Annex II, paragraph 5 and Annex X, paragraph 1.1 c). In fact, the surveillance and supervision of accidents, operated by competent authorities of the Member States, are subsequent to the phase of commercialization and they occur either through random controls or reports from the parties.

Such method of subsequent controls on the entrance of devices into the market has led to the drafting of a policy that provides more specific requirements to keep records of the devices. For instance, attention was driven towards the inclusion of a deadline that represents a specific time limit required for keeping the documents, thus providing a base for the application of the penalty when rules are broken.

Furthermore, to ensure effective, proportionate and dissuasive force to sanctions, the cases for the use of special penal sanctions have been limited to two: non-disclosure of serious accidents and failure to comply with mandatory provisions of the competent authorities. The formula "unless the act constitutes a crime", was maintained to permit the application of any additional penalties and sanctions in cases of criminal offenses affecting constitutionally guaranteed interests such as health (e.g. Articles. 441, 582, 589, 590 of the Italian Penal Code).

In order to allow competent Italian authorities to run efficient and fast actions of monitoring and supervision to protect public health, two directions have been followed:
- updating of the rules on special measures for health monitoring and safeguard clause (Article 8-8-a and b, L. Decree N.507/92 - Articles. 7:13-ter of L. Decree no. 46/97);
- the provision of pecuniary sanctions for the subject responsible of improper or absent CE marking, alongside administrative measures restricting market entry as well as imposing the withdrawal of the product for evaluation (Article 9 L. Decree no. 507/92 - art. 17, Leg. n.46/97).

Over 90 sheets were drawn for the evaluation of both gravity and extent of the breach of regulations. Many factors were considered in preparing these sheets such as the territorial extension and potential duration of the infringement, the level of adverse effects, the potential illegal economic benefits obtained by the subject responsible, whether the guilt originated from intention or negligence, individual or collective punishable behavior.
Different categories of subjects potentially involved in the infringement were considered: from the manufacturer to the individual health professional (taking into account the degree of consciousness of the act, its consequences and the potential economic benefit that such persons might have drawn from the unlawful conduct).

Hence, five levels of indicators were identified for the violations contained in the text which, to ensure effective deterrence, have been associated to five levels of minimum amount of the penalty, setting the highest amount at six times the first.
The central subject in the regulation of medical devices, as it has been outlined for years at EU level, is the manufacturer/authorized representative.
Most of the obligations concern this category: manufacturers have to notify the Ministry of Health address and description of devices and they must provide all data necessary to identify these devices, along with label and instructions for use.

If the manufacturer is located outside the European Union, he must explicitly designate a single subject, natural or legal person established within the Union, who acts on behalf of and can be addressed to instead of the manufacturer.
Manufacturers are also subject to sanctions ranging from EUR 500 to 128,400.
Among the merely economic implementations, it is also included the payment, to be carried out by 30 April of every year, of a 5% contribution for self-assessment for promotional activities directed towards health care workers. (The obligation to pay is governed by 1st c. 409, Lett. d) of Act No. 266/05, as amended by Article. 1, c. 825, Lett. b), Law No. 296/06).

The contribution is borne by all "companies that produce or market medical devices in Italy, including in-vitro diagnostic medical devices and custom made devices". The rule applies to the promotion of a product by "doctors, health professionals, including executives of health institutions and pharmacists", if the product meets the definition of "medical device" and is labeled and marketed under the EU sector directives.

"The total expenditure borne in the previous year" is the basis of assessment for contribution. It includes specific "cost items" as by Technical Annex to the Ministerial Decree 23/04/2004 - relating to the pharmaceutical field, but to which this law explicitly refers to - excluding "net costs for the staff".
Failure to pay leads to a penalty of EUR 7,500 to 45,000, besides the sum already due, increased by 5% for each month of delay.

The most relevant administrative penalties are those affecting subjects who place into the market or service medical devices without CE marking or attestation of conformity (both the manufacturer's declaration and any certificate issued by the Notified Body).
In such case, the penalty ranges from EUR 21,400 to EUR 128,400 for any subject placing in the market, selling or servicing non-compliant medical devices, as well as for the manufacturers of custom made devices that are non-compliant or without the declaration required in the relevant technical Annex.
These sanctions are aimed at protecting and ensuring the so-called "public confidence" in the regularity of CE marking. Just as serious are sanctions for the manufacturers/authorized representatives that mark a device inappropriately, as in the case of products falling outside the definition of the Decree, or unduly, because the product does not meet all essential requirements.
Medical devices not bearing CE marking are always subject to administrative seizure.

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