CE Mark of Medical Devices:
changes after the adoption of the new Directive 47/2007

In the EU, the market of the medical devices (MD) is regulated by the Medical Device Directives. As far as dental apparatuses and implants are concerned, the applicable directive is the MDD 93/42EEC, which has recently been amended by the Directive 2007/47/EC, published in the Official Journal of September 21st, 2007 and entered into force on October 11th, 2007.
According to the second subparagraph of Article 4(1) of Directive 2007/47/EC, the Member States "shall apply [the transposition measures] from March 21st, 2010". The consolidated Directive has become mandatory as of March 21st, 2010, without any provision for a 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.

Although the directive 93/42 has not been radically changed, a series of clarifications and innovations have been added to improve the interpretation of procedures for the evaluation of these products across Europe. The novelties introduced by the 2007/47/EC will have implications for manufacturers, Notified Bodies and national authorities.

The changes concern, among others, the essential requirements which medical devices must satisfy in order to be legally placed on the market, the corresponding conformity assessment procedures and the classification of devices. Following are some of the changes who may have an impact on manufactures and/or final users.

• INTENDED USER: The obligation to specify the intended user identifies the need for medical devices manufacturers to tailor their devices and the relevant instructions-for-use to the expected skills and knowledge of the user. This requirement is particularly important for devices intended for non-professional use.

• CLINICAL EVALUATION: The new directive emphasises the need for clinical evidence for all devices. All devices now require these data, including Class I devices. Moreover, this imposes more stringent requirements as to what constitutes "clinical evidence" and calls for stronger enforcement by authorities. Annex X on Clinical Evaluations has been significantly amended. As a consequence, manufacturers should now analyse and review the clinical part of their design dossier to identify any issue that needs to be further investigated.

• STAND ALONE SOFTWARE: the Directive 2007/47/EC specifies that software in its own right, 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, is a medical device. The software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. The harmonized standard EN IEC 62304:2006 "Medical device software - Software life cycle processes" can be used to comply with the new provisions. In addition, software shall be classified following the classification rules set out by the 93/42. Note that Stand alone software is considered to be an active medical device (Annex IX, rule 1.4). As an example, software packages that allow to perform implant simulation on PC are now considered active therapeutic medical devices. Therefore, such stand alone software shall bear the CE mark to indicate their conformity with the provisions of the Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose.

• ERGONOMIC DESIGN: to ensure patient safety, ergonomic design is considered an essential requirement of medical device. Ergonomic features of medical products become the focus of attention in the development process. The harmonised standards EN 60601-1-6 and EN 62366:2008 can be applied to demonstrate the compliance with this essential requirement.

• SINGLE USE: Particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients' safety or health. Thus, for single-use devices, the manufactures shall provide information on known characteristics and technical factors that could pose a risk if the device were to be re-used.

• CONFORMITY ASSESSMENT: Manufacturers of Class I Sterile and Measuring devices now enjoy more flexibility in selecting a route to compliance, as they will be given the option to select a full quality assurance conformity assessment module (Annex II of the 93/42).

• e-LABELLING - Medical device labelling in the EU poses a challenge for manufacturers, who must provide Instructions for Use (IFU) in several languages. Currently, most IFU are provided in paper format, which can be very long. The term "e-labelling" refers to innovative means for providing IFU in an electronic format. The amendment introduced by Directive 2007/47/EC acknowledges that a process should be provided to allow information supplied by the manufacturer to be available by other means. It could potentially allow to provide the IFU on a CD or via other electronic means, eliminating the several different paper versions now required.

Manufacturers are required to declare the conformity of their product with the Directive in form of a Declaration of Conformity. Declarations of Conformity issued as of March 21st, 2010 are automatically deemed to refer to the relevant directive in its revised version. As of that date, the manufacturers must be able to prove their compliance with all requirements of the revised Directive which are applicable to their respective product. If manufacturers have placed on the market, or put into service, products complying with the new requirements prior to March 21st, 2010, they should have documented that their Declaration of Conformity states compliance with Directive 93/42/EEC, as amended by Directive 2007/47/EC. If not, as in the case of Declarations of Conformity issued before October 10th, 2007 (date of publication of the 2007/47 amendment), the Declarations should be reissued, according to the new requirements of the revised Directive. When a Notified Body is involved in the conformity assessment (e.g. for devices class II or higher), a similar procedure has to be followed for the CE Certification issued by the Notified Body. A guidance for a uniform practice throughout the EU on the issuing of new Declarations and Certifications can be found in the following document of the Commission's Services: IMPLEMENTATION OF DIRECTIVE 2007/47/EC AMENDING DIRECTIVES 90/385/EEC, 93/42/EEC AND 98/8/EC, of June 5th, 2009.

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