

2. ITC Korea

Recently Notified Body Operating Group (NBOG) issued guide documents according to directive amendment and NBs should follow these guide documents.

Therefore we inform that title of five guide documents and NB documents and procedures expected to change.

NBOG's Best Practice Guide

2009-1

Guidance on Design-Dossier Examination and Report Content

2010-1

Guidance for Notified Bodies auditing suppliers to medical device manufacturers

2010-2

Guidance on Audit Report Content

2010-3

Certificates issued by Notified Bodies with reference to Council Directives

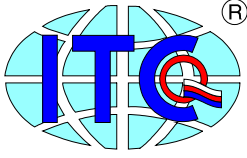
- 93/42/EEC on medical devices (MDD)
- 98/79/EC on in vitro diagnostic medical devices (IVD)
- 90/385/EEC on active implantable medical devices (AIMDD)

CL2010-1

Checklist for audit of Notified Body's review of clinical data/clinical evaluation

According to above guide documents, expected changes of Notified Body document and procedure are as below.

- If necessary, change in the audit report form
- If necessary, change in the certificate contents
- Clarification of criteria whether a visit for audit is necessary to outsourcing provider or not
- Reinforcement of audit checklist for clinical evaluation



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**Reception: Head of the center for Medical Devices Information Technology
Korea Testing Laboratory (KTL)**

Wish you tremendous success in everything you do.

According to amendment and effectivation of medical device CE marking direction, our policy directions to answer you requested are as below.

1) Changes in the certification procedure and policy before and after revision

There is no change in the certification procedure according to amendment of Medical Device Directive.

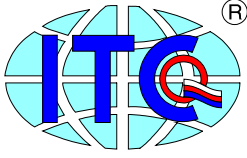
In case of CE certificate issued before 21th March 2010, the certificate is valid during available period (the first five years from the date of issue) if conformities are verified through annual surveillance audit. In other words, unless there are no the changes in product, relocation of manufacturing sites and so on, the new reissue of a separate certificate according to revised directive is not required.

And because product and model name marking which is requirement of revised directive has been previously applied in certificate issued by us, change in the certificate does not occur.

In the new certificate issued after 21th March 2010, 2007/47/EC does not mentioned. The reason is that 2007/47/EC is not a new directive and revised not entire contents but some of 93/42/ECC. So, 93/42/EEC which is existing directive is still being used on the certificate.

2) Things to do and essential particulars for the company having CE certificate issued by us

In case of the company which has CE certificate issued before 21th March 2010, they should



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change the technical file and system to implement and maintain according to revised directive (2007/47/EC) before 21th March 2010 (the time to compulsorily apply the revised directive).
The compliance with revised directive is verified at regular annual surveillance audit.

At surveillance audit clauses to assess compliance with revised directive are as below.

- If applicable to other directive of medical devices, that is PPE directive and Machinery directive, check whether applicable directive is applied
- Check compliance with revised essential requirement
- Check whether clinical evaluation is conducted, the following result is documented and the clinical data obtained through post market surveillance is updated
- Check whether name of product and model is clearly marked on Declaration of Conformity
- If design, manufacture, final inspection, product testing, etc are performed by 3rd party, check whether there is the way to monitor the effective operation of quality management system
- Check in case of implantable medical device whether manufacturer store the documents related quality at least 15 years after final product is produced
- In case of the product needed to change the class according to revised directive, check whether the changed class is applied.

The revised technical document and quality document which reflect the above information will be checked at the time of audit.

END.