

IMPORTANT – this concern your CE certification!

Information from your Notified Body on the regulatory changes to the Medical Device Directive

The MDD 93/42/EEC is being revised. The changes are listed in the change directive 2007/47/EC. All manufacturers must comply with the revised directive at the latest **21 March 2010** when the changes become mandatory. Below is information about some of the changes and how your certification will be affected.

What will happen with the existing EC certificates?

- As a general rule, the existing certificates will continue to be valid. The MDD directive is still 93/42/EEC.
- All manufacturers shall comply with the revised MDD at the latest 21 March 2010. This applies also to existing devices – for all devices, you shall be able to show that they conform to the new requirements by this date.
- There will be no change in the audit schedule in most cases. Conformity to the new requirements will be assessed at the first audit after 21 March 2010. At audits before that date, auditors will note an “Opportunity for improvement” if they identify anything that will become a non-conformity after 21 March, but there will be no systematic evaluation to the revised directive before that date unless it is a special case as described below.
- The exception from the general rule is when the classification of a product changes and will require a new conformity annex or Design Dossier review. To help us identify these cases, please fill in and return the enclosed form.
- The existing certificates for those special cases that need an upgraded assessment to a new Annex or a Design Dossier review will be withdrawn on 20 March 2010. Before that date, a new assessment including the new requirements needs to be completed so that a new certificate can be issued from 21 March 2010.
- The cost of any extra activities that will be required by the Notified body such as Technical file reviews, Design Dossier reviews and/or additional assessments will be quoted when the need for the extra activities have been identified.
- On a voluntary basis, a client can request to be assessed to the new requirements before 21 March 2010. The Notified Body will perform the assessment if possible.

The above points are based on the information available so far from the different authorities. If the authorities publish any new decisions or guidance documents on this issue we may need to revise the procedures.

What are the new requirements?

All manufacturers need to study the revised Directive to identify the new and changed requirements that are applicable to them. The actions required to comply with the new requirements need to be identified and executed and the necessary documents need to be updated to show compliance. Most important changes are highlighted below:

- Retention time for documentation has been increased to 15 years for implantable devices.
- There are a number of changes and additions to the Essential requirements in Annex I. Some examples:
 - more user focus and focus on ergonomic design
 - in avoiding leaking substances that may pose a risk to patients, special attention shall be given to substances that are carcinogenic, mutagenic or toxic to reproduction; there are specific

requirements and restrictions concerning use of phthalates in some medical devices;

- a requirement for state of the art validation of software, both stand alone and embedded (this is valid irrespective of device class and Annex used)

- demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. (Please note the differences between clinical evaluation and clinical investigations/clinical trials)

- If a device is also at the same time machinery or personal protective equipment, applicable requirements of the Machinery Directive (2006/42/EC) or the Personal Protective Directive (89/686/EEC) respectively need to be taken into account, but the conformity route is only through the MDD.
- Additional requirements for information in the manual for known hazards with reuse of devices marked "single use".
- Annex X regarding Clinical evaluation has been extensively rewritten and requirements relating to clinical data such as post-market surveillance have also been added in other Annexes. A critical evaluation of clinical data is necessary; clinical data must be actively updated with data obtained from the post-market surveillance.
- Emphasis on the importance of the manufacturer's control that the quality system is effective also when activities are performed by a third party (control of sub contractors and outsourced processes)

Please note that the above is not an exhaustive list; also for the actual wording you must consult the directive.

Technical file reviews by the Notified Body

As your Notified Body, we have performed reviews of your Technical files on a sample basis as this has been required by our Competent Authority. In the revised directive, this requirement is now clearly stated and with a basis for sampling, it has now been included in the conformity assessment procedures described in the directive. The Notified Body is required to make a sampling plan for Technical files for class IIa and IIb devices for each five year period. The sampling regime is more stringent for the class IIb devices.

Before 21 March 2010, the Notified Body will review your MDD – Product list and decide on a sampling plan. We will do this in cooperation with you, as we will need your help in defining your device subcategories (for class IIa) and generic device groups (for class IIb). The sampling plan will be used from 21 March 2010.

Already beginning this autumn we will perform reviews of Technical files including the new requirements on a voluntary basis. The advantage with going through a review early is that you will get an early feedback on if you have addressed all of the new requirements and in an appropriate way.

Useful link:

http://ec.europa.eu/enterprise/medical_devices/legislation_en.htm

A consolidated version of the MDD including the changes of the 2007/47/EC can be downloaded from this site (the EU commission's). The changes are marked with M5 throughout the consolidated version. This site also contains links to the Meddev guidance documents, harmonised standards and much more.

www.lakemedelsverket.se

This is the website of the Swedish Competent Authority ("Medical Products Agency"). Some general information on the regulations in English. Contact information and forms for reporting of incidents.

www.medtechinfo.com/Turnpike.aspx?id=85

On this side we will upload information about the revision from us as your Notified Body.

Questions

As a Notified Body, strict requirements regarding non-conflict of interest prevent us from offering specific solutions on how you shall fulfil the new requirements but we may help you understand the revised requirements. Please direct any questions you may have to Intertek Semko's email address: <mailto:medtechsweden@intertek.com>

Information needed!

Please complete and return the enclosed form. This will enable us to determine if any special assessment activity is required and to plan to have this activity completed before the 21 March 2010 deadline. It will also help us determine the sampling plan for Technical file reviews. The form should be completed and sent to Intertek Semko **by June 30.**

Intertek Semko AB, NB 0413:

<mailto:medtechsweden@intertek.com>