

Med-Info



Regular Information Bulletins for the Medical Device Industry

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Transition to EC Directive 2007/47/EC

On March 21, 2010, the EC Directive 2007/47/EC will become effective. This Directive will have a big impact on the Directives 90/385/EEC and 93/42/EEC. All manufacturers declaring conformity of their products to either of these EC Directives should be aware of the following: **Medical devices according to 90/385/EEC or 93/42/EEC must also comply with the new EC Directive starting March 21, 2010, otherwise the products cannot be placed on the European market.**

Clear requirements so far

Classification of Medical Devices

Some medical devices will need to be re-classified as the classification rules of the MDD 93/42/EEC will be changed. In some rare cases, devices could become Class III devices. Then a different conformity assessment procedure will be applicable.

Essential Requirements

The essential requirements will change. Additional requirements as well as modified and newly defined requirements will have an impact on existing assessments. All manufacturers shall evaluate all their CE-marked products and compare the existing evidence of compliance with the new essential requirements.

Technical Documentation

The requirements for the content of technical documentation (technical file, design dossier) will change. Additional documents will become part of the technical documentation, and existing documents may have to be updated. Please compare your technical documentation with the new description of the technical documentation.

Declaration of Conformity

All existing Declarations of Conformity will become invalid on March 20, 2010. All CE-marked products placed on the market starting March 21, 2010 will need to be covered by a new Declaration of Conformity. The Declaration of Conformity has to include a statement that the requirements of 2007/47/EC are fulfilled.

European Representative

The new EC Directive 2007/47/EC will allow manufacturers to only have one European representative per medical device. If you have more than one medical device, you may use several different European representatives. However, please make sure that you only have one representative for one specific medical product. The new EC Directive may also have an impact on the contracts you have with your European representative(s). Here is the explanation of the change as stated in the Directive: *"To ensure that, where a manufacturer does not have a registered place of business in the*

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Community, authorities have a single individual person authorized by the manufacturer whom they can address in matters relating to the compliance of the devices with the Directives it is necessary to introduce an obligation for such manufacturers to designate an authorized representative for a device. This designation should be effective at least for all devices of the same model."

Assesment of Technical Files

At the latest starting March 21, 2010, every Notified Body will have to assess technical files as part of the audit. However, it is still unclear how many technical files are required, how intense the assessment must be, and when the Notified Body has to start applying the new rules (see below).

Machinery Directive 2006/42/EC and Personnel Protective Directive 89/686/EEC

Both EC Directives will become applicable for some medical devices. At the very latest on March 21, 2010, compliance with the essential requirements of these Directives is required for those devices that fall under the definition of one of these Directives. However, it is still unclear how the transition to these requirements with regard to time schedule and necessary documentation needs to be done.

Clinical Data

The new Directive 2007/47/EC will change the requirements for and the handling of clinical data. Additional requirements will be defined in the future. This is also applicable for existing medical devices. In some cases, this may have a big impact on your documentation

Unclear requirements so far

There are still several open questions for which the European Commission, the Competent Authorities, and the Notified Bodies do not have a common interpretation.

Sampling of Technical Files for Assesment

The sampling scheme for technical file assessment is not clear and still under discussion. So far, the text of the new EC Directive seems to be clear: One sample of each group of medical devices must be assessed by the Notified Bodies during the initial audits; further samples must be taken during surveillance. However, the definition of "group," and the number of samples during the surveillance activities are still unclear.

Depth of Technical File Assesment

The depth of the assessment is also very unclear and under discussion. Assessment times from a few hours up to several days are possible.

Grouping of Medical Devices

Because of various discussions regarding the sample scheme and the depth of technical file review, it will be very important for manufacturers to group their medical devices. Grouping may be based on similar intended use, similar materials used, similar technologies, or similar manufacturing processes. Even though grouping is not yet clear, we encourage our clients to start working on this issue together with us.

New EC Certifications by Notified Bodies

Up to now it is under discussion whether the existing EC certificates issued by Notified Bodies will remain valid after March 20, 2010, or whether new certificates with reference to the new EC Directive must be issued. The German Competent Authorities do not intend that the German Notified Bodies will have to issue new certificates, but other European Competent Authorities might have a different point of view.

Due to the current discussions within Europe, it is not possible to give a definite answer. Implementation rules that seem to be clear today may be changed tomorrow. Answers provided today may need to be redefined tomorrow.

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Recommendations to our Clients

1. Start working on the implementation of the new EC Directive now!

2. Accompany the implementation of the new requirements with internal quality management tools such as internal audits or management reviews.

3. Prepare a schedule for the assessment of the technical documentation for each product or product group. If your device is classified into Class III and a Design Dossier was assessed by TÜV SÜD, make sure that an updated Design Dossier – if necessary – is sent to us in time. If you have an EC Type Examination certificate, make sure that necessary assessments will be carried out by TÜV SÜD.

4. In some cases you might have to prepare new test protocols and reports. Sometimes such tests must be carried out by a third party. Please take into consideration that at the end of this “transition period,” mainly at the beginning of 2010, such third parties may be very busy and might not be able to provide their service on time.

5. There are some medical devices that will become Class III devices. For Class III devices, different conformity assessment procedures apply. In some cases, intensive assessment by a Notified Body will be mandatory (e.g. Annex III, Annex II.4). Make sure that these new assessments are planned well in advance and that you do have the necessary EC certificates at hand.

6. Make sure that you have finished your conformity assessment according to the new Directive 2007/47/EC for all your products.

7. Stay in close contact with us.

8. Screen publications with regard to new developments.

9. Visit our website www.tuev-sued.de/MDD for the latest news.

TÜV SÜD America Audit Strategy until March 20, 2010

1. Starting at the very beginning of June 2009, TÜV SÜD will voluntarily provide the service of adding the new EC Directive 2007/47/EC to the scope of audits if the current scope includes 90/385/EEC or 93/42/EEC.

2. If you want to include 2007/47/EC in the audit, the following will apply:

- TÜV SÜD auditors will ask for an implementation plan for the new requirements. You should have a plan ready with a detailed description of how the requirements of the new Directive will be implemented. This includes an analysis of the current quality management system, and a comparison with the new requirements.
- TÜV SÜD auditors will verify the implementation of the plan.
- TÜV SÜD auditors will rate findings identified as being against the new Directive as “improvement potentials” and will note these findings in the audit report as such.
- During the course of the very first audit after March 20, 2010, TÜV SÜD will verify that all requirements of 2007/47/EC are fulfilled. Improvement potentials identified before March 21, 2010, could become nonconformities if corrections and corrective actions will not have been implemented, and the interpretation of the requirement will not have been changed.



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