

3rd Edition - Summer 2011



Product Service

Choose certainty.
Add value.

MEDICAL :: Talk



INSIDE:

- Changes Ahead
- Interesting Medical Facts
- What is proposed for ISO 13485:2003
- Is it mandatory to have medical electrical equipment tested?

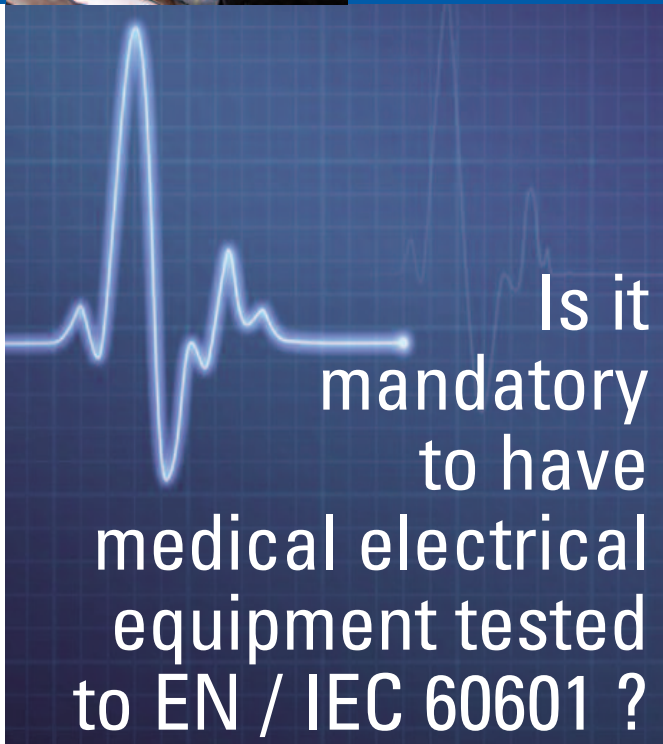
www.tuvps.co.uk



Dear Readers:

Welcome to the third edition of MEDICAL:Talk, TÜV SÜD Product Service's newsletter on the Medical devices industry. This newsletter is designed to keep you informed about regulatory changes within the industry, as well as keep you updated with our latest activities and services.

We trust you will enjoy our first issue. If you have any questions on any of the related topics please contact us, and we will be happy to help.
Jean-Louis Evans - Managing Director



ISO 13485:2003

Changes are being proposed by ISO which may affect this standard (as well as ISO 14971).

The proposals involve a reformat of the template used for the standard and may include some mandated requirements, which may go above and beyond the regulatory requirements. You can obtain some further information by accessing the following link.

<http://www.aami.org/Applications/Com+mitteeCentral-app/Documents/210n3791.pdf>

What the proposed changes will actually mean is not known at this stage and the work programme has not yet been authorized by ISO. So you should keep an eye on developments over the coming months.

IVD manufacturers

Many changes have taken place recently affecting the non IVD medical device world. However, changes are also afoot in the world of IVDs.

A proposed recast was issued for public consultation. The following link will take you to the public consultation document. Although the closing date for comments has now passed, this document will be of benefit to those who may not have seen the proposals.

http://ec.europa.eu/consumers/sectors/medical-devices/files/recast_docs_2008/public_consultation_ivd_final_en.pdf

Feedback from the consultation, which closed on 15th September 2010 indicated that the world of genomics will feature more intensively in the new directive.

Choose certainty. Add value.

The safety of most medical electrical equipment is demonstrated by compliance with 60601-1, the applicable collateral standards and any Part 2 or other specific standard that relates to the item under consideration.

Is third party testing mandatory? The answer is no, testing is not mandatory, but compliance is. (Equivalent safety is allowable, but extremely difficult to establish.)

The next question is, can one ensure compliance without testing? The only possibility is by a rigorous design process which allows no room for error. This means in turn that the designer must be completely familiar with all the requirements down to the smallest detail, and the construction of the equipment and the components must be error free. This is potentially an unrealisable goal for all but the simplest equipment.

An alternative for the biggest companies is to do in-house testing with a fully equipped lab, a full complement of calibrated test instrument and an experienced tester.

For most manufactures, however, the only sensible solution is to go to a competent accredited third-party test house such as TÜV SÜD Product Service.



Change happens all the time, but managing the changes requires some effort to make it effortless.

This past year has seen a number of changes both within TÜV SÜD Product Service and among our clients. The same question quite often comes up from clients – “What changes do I need to notify and what do we need to do?” This is a good question and one that cannot be answered in just a short sentence or two, as the nature of the change that needs to be notified will depend on what type of certificate is affected; however we will cover the most common changes, with the help of a few changes.

The Directive states that notification of “significant” changes are required before they take place. This allows us the opportunity to work with you on the change.

The following are some examples of significant changes and a brief explanation of why they need to be notified to us.

New management representative

This role is a key function in terms of the quality system and is the only function within ISO 13485:2003 where the role of the management representative is clearly defined.

Additionally this is the person that we usually have as the company contact, therefore we need to update our databases to reflect the change in contact details.

New name and/or address.

A new name and/or address will result in the need for a change of certificate. Clearly these two changes are not something that takes place overnight, so please let us know of your intentions to change your name and/or address so that we can explain what information will be required for a new certificate.

The Medical Devices Directive requires that planned changes are advised to the Notified Body to enable a reasoned decision on the ongoing compliance of the approvals already held. Therefore please tell us about the planned change to the name and/or address. Informing us after you have moved or changed name, does not technically meet the requirements of the directive of informing of planned changes. It also restricts the available time when an auditor or technical expert is available to process the change.

For EC and other regulatory certificates, if the name and address is not the same as the product label / IFU, then technically no product can be

sold using the new name and/or address. Therefore an early notification to us will allow us to help you with the change strategy and to plan a visit to your new site to confirm that the change in address has not affected the compliance status of the quality system underpinning the CE mark.

Our aim is to keep the time it takes from the notification of a change of name and/or address to the issue of a new certificate to a minimum.

For non regulatory ISO certificates, it is slightly different, as the ISO certificate (except those with the SCC accreditation for Canada) is not a legal requirement. You can continue to trade with a certificate that does not reflect the new name and/or address, but your customers could require a new certificate urgently. Again notifying us of your intention for a new name and/or address will help us to plan the change strategy. An immediate audit may be required or it could be delayed until a future date.

Fit / Form / Function

The extent of the change to a certified product to be notified will depend on what is planned to change and the type of certificate you hold. So, for example, we do not need to be informed of product changes on an ISO 13485:2003 certificate or if the technology has not changed, the scope of certification covers the change. However, if you hold an EC certificate for a class III device, then clearly any change to the product must be notified.

Then we have grey areas such as class 1 sterile / measuring devices, class IIA and IIB devices, OEM-PLM arrangements / article 12 certificates.

The notification of the planned change(s) required is based on the three F's – “FIT – FORM – FUNCTION”

So, if the planned change affects any of these three, you must notify us. The approval process may be a simple email, an in-depth review of the change prior to approval, review of the change at the next audit or a special audit to review the change.

However, please inform us of the planned change, as there is nothing more frustrating than to go through a two year design project and be ready for the launch to the market, and then to find that there is a six month delay as we require some additional testing and the change requires a six month review prior to approval.



Interesting medical facts Did you know?

Why has the inventor of Super Glue™ been in the news this year?

The inventor "Harry Coover" died earlier this year. The incredibly stable adhesive known as Super Glue™ was invented by accident in 1942 by Dr. Harry Coover. Today the substance is somewhat of a household necessity, with uses ranging from simple woodworking and appliance repair to industrial binding and medical applications such as skin and tissue adhesives, wound care, skin sealants

What is the most popular consumer product ever invented?

Aspirin. No doctor's office or medicine cabinet is complete without a supply of aspirin, the world's most popular and in many ways miraculous painkiller. This multi-purpose drug was first stabilized and patented during a three-year span from 1897-1900 by Felix Hoffman, a chemist with Friedrich Bayer & Co. in Germany.

Born on January 21, 1868, in Ludwigsburg, Germany, Hoffman studied pharmacy and chemistry at the University of Munich from where he graduated in 1893 with a doctoral degree. In 1894 he began working as a chemist for Bayer in Elberfeld, Germany. His father's suffering from the pain of arthritis inspired him to seek a chemical substance that could safely treat everyday pain.

Too much sugar is bad – but who helped you find this out at home?

A distinguished chemist and promoter of science, Helen Murray Free invented a number of tests that revolutionized certain types of analysis in the laboratory and diagnosis of diabetes at home. Along with her husband Albert Free, whom she married 3 years after starting work at Miles Laboratories, she became the world's leading experts on urinalysis, an essential clinical procedure with countless applications. Free first developed dry reagents for use in laboratory urinalysis that are now, in tablet form, standard around the world. She went on to develop more consumer-oriented devices. The most important of these was a "dip-and-read" test that for the first time allowed diabetics to monitor their blood glucose level instantly and at home.

