EDITORIAL

Dear Reader,

Welcome to a special issue of the Medical Devices Newsletter. Within this issue you will find the latest news from the SGS Medical Devices Team, including:

- Major changes in Medical Devices CE Certification for Notified Bodies starting in 2014
- Current Edition of the “Medical Devices Regulations in the main Global Markets” white paper
- New Webinar about the Changes to CE Certification of Medical Devices

We hope you find this issue informative and useful!

Best regards,

SGS Medical Devices Expert Team

SPECIAL POINTS OF INTEREST:

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MAJOR CHANGES IN MEDICAL DEVICES CE CERTIFICATION FOR NOTIFIED BODIES START IN 2014

Changes to the way Notified Bodies audit all manufacturers of medical devices and to the supervision of Notified Bodies will significantly change the nature of CE marking certification from 2014 onwards.

In the wake of the PIP breast implant scandal the EU Commission has been considering for some time how to impose tighter control on both manufacturers and Notified Bodies. After considerable discussion, the EU Commission adopted two important documents both dated 24 September 2013 and published in the Official Journal on 25 September 2013.

NEW DOCUMENTS FROM THE EU COMMISSION

The two new documents published by the EU Commission are designed to use the current legislation to impose a tighter regime of audits and technical documentation assessment on manufacturers of medical devices. In addition, the documents also impose a higher degree of technical competency and adherence to MEDDEV documents on Notified Bodies. The two Commission documents are:

• Commission Recommendation on the audits and assessments performed by Notified Bodies in the field of medical devices 2013/473/EU.

These affect manufacturers of active implantable medical devices, medical devices and in vitro diagnostic medical devices. The Recommendation states:

‘The interpretation of those provisions [i.e. the medical device directives] and the behaviour of notified bodies designated in the field of medical devices differ. Therefore, this Recommendation should set benchmarks for assessments and unannounced audits by notified bodies and respond to the most frequent shortcomings of the current practices.’

MAJOR CHANGES TO AUDITS AND QUALITY MANAGEMENT SYSTEMS (QMS)

All of the following points should be considered in relation to the new legislation:

a). There is a high emphasis on the need to audit the premises of the (legal) manufacturer and also critical subcontractors and suppliers. This will lead to the need to visit all manufacturers annually including own brand labellers and to increased audits of critical subcontractors and suppliers where the manufacturer’s control is judged inadequate.

b). Notified Bodies will need to assess more critically whether the organisational structure and the qualification and competence of managers and staff is adequate to ensure compliance. Major failures of compliance will result in the Notified Body questioning whether the manufacturer has adequate regulatory, quality or technical expertise within the organisation.

c). In future, it will not be sufficient to demonstrate that all devices are correctly classified, that technical documentation is complete (etc.). The manufacturer must have up to date procedures that describe all the processes that ensure regulatory compliance.

d). Risk management will continue to be considered a critical aspect of the manufacturer’s QMS and the application of the process to devices will be regularly audited. Manufacturers should be aware that ISO 14971 alone is not sufficient and the EU regulatory
requirements of reducing risks ‘as far as possible’ and applying safety principles ‘compatible with the state-of-the-art’ must also be incorporated into the risk management process.

e). Clinical evaluation for medical devices and performance evaluation for in vitro diagnostic medical devices will remain a high priority, so manufacturers should expect their processes and their decisions and documented justifications to be challenged more often during audits.

f). The Recommendation provides a non exhaustive list of critical processes on which parts of the audit will focus: ‘design control, establishment of material specifications, purchasing and control of incoming material and components, assembling, software validation, sterilisation, batch release, packaging and product quality control.’ The expectation of the Notified Body will be that the manufacturer must demonstrate tight control even if this activity is subcontracted.

g). Notified Body audits may in future include in the audit a reconciliation check of purchased quantities of critical material or components against production. This will be of particular importance for high-risk devices.

h). Manufacturers will be expected to use all available sources of post-market surveillance data including (where applicable) distributors, users and patients.

i). The Recommendation makes it clear that Notified Body audits should be annual, a frequency already adopted by most Notified Bodies.

j). The quality manual and policies must demonstrate that the (legal) manufacturer, including when there is an own brand arrangement, actively retains responsibility for all the Directive requirements and all the critical processes. All manufacturers must have access to relevant technical documentation and must make all physical manufacturing sites available for the Notified Body audits. Current guidance on own brand labelling will have to be amended to reflect these changes.

**UNANNOUNCED AUDITS**

All of the following points should be considered in relation to the new legislation:

a). Unannounced audits will be carried out in a random manner once in every three-year period on all manufacturers of medical devices of all classes. Manufacturers of high-risk devices and those that are frequently noncompliant will have this frequency increased to 18-month periods.

b). Manufacturers will have no prior notice and most audits will last one day and involve a team of two or more auditors.

c). As the main manufacturing site will normally be the location of the unannounced audit, this will in some instances be the location of the critical subcontractor and not the location of the (legal) manufacturer.

d). Unannounced audits will comprise two elements: a sample check to ensure recent or current production is in conformity with the technical documentation, meets specifications and that critical components and materials are traceable; and an audit of two critical processes as listed in f) above with the exclusion of software validation.

e). Testing of the chosen sample(s) will usually be required to establish conformity and this can be undertaken by the manufacturer and witnessed by the Notified Body during the audit, or the Notified Body may take away samples for subsequent test. For devices that do not require an EC design examination or type examination, one device will be taken. For high-risk devices, a minimum of three will be examined and tested. Sampling and testing procedures will have to be defined in advance and this is an area of the Recommendation that will need further clarification.

f). Unannounced audits and the accompanying testing represent the major additional direct cost to the manufacturer of these EU Commission changes. The additional cost will vary greatly from manufacturer to manufacturer but will in many cases increase certification costs over a three-year period by between 20% and 50%.

**MAJOR CHANGES TO TECHNICAL DOCUMENTATION AND TECHNICAL FILE ASSESSMENTS**

All of the following points should be considered in relation to the new legislation:

a). There are no new requirements for manufacturers to document, and no changes to, the Essential Requirements. However, the strong expectation from Notified Bodies will be that all MEDDEV and NB MED guidance is strictly followed. This will include documented justifications for all statements, clearly defined medical purpose, clinical evaluation, post market clinical follow up (etc.). So manufacturers can expect to be challenged on decisions such as the decision not to undertake a clinical investigation or post market clinical follow up, or to classify as a medical device a product that contains an active ingredient.

b). Manufacturers must ensure that all technical documentation and certification can be ‘unequivocally’ related to devices types and variants, and to individual products via a product identification system.

c). Although the Essential Requirements in relation to risk have not changed, the Recommendation contains a clause reminding manufacturers and Notified Bodies on the EU view of risk (as also clarified in Annex Z of EN ISO 14971:2012). This includes the requirement to reduce risks ‘as far as possible’ and that safety principles applied must be ‘compatible with the state-of-the-art’. This will be the expectation of the Notified Bodies.

d). When major deficiencies are found in technical documentation manufacturers will be expected to correct the deficiency but also address the deficiency in their QMS that gave rise to the inadequate documentation.
MAJOR CHANGES FOR NOTIFIED BODIES

All of the following points should be considered in relation to the new legislation:

a). New Notified Bodies, and existing Notified Bodies extending their scope or having designation renewed, will be subject to much more scrutiny than before including an audit team comprising of three different Competent Authorities and the EU Commission.

b). Surveillance of Notified Bodies will now include annual assessments of their reviews of manufacturer’s clinical evaluations.

c). Notified Bodies can, like manufacturers, be subject to unannounced audits.

d). The EU Commission and Competent Authorities will actively investigate complaints about the competence of Notified Bodies.

e). Impartiality and conflict of interest requirements have increased and now preclude the Conformity Assessment Body and all its personnel from having offered or provided consultancy within the last three years to a manufacturer being certified, its supplier or a competitor. This effectively will end the offering of any consultancy by Notified Bodies or their parent companies.

f). Although contractors can additionally be used, Notified Bodies must have within their organisation all the technical, clinical and scientific expertise needed for all devices types being certified

CHANGES TO CONTRACTUAL ARRANGEMENTS BETWEEN NOTIFIED BODIES AND MANUFACTURERS

All of the following points should be considered in relation to the new legislation:

a). Agreed periods of non-operation will have to be defined when unannounced audits cannot take place. It will be the manufacturer’s responsibility to inform the Notified Body of any change of dates.

b). The absolute right to make unannounced audits to the sites of manufacturers, or any predefined critical subcontractors, will be included in contracts (most contracts will already include this in a more general way).

c). The Recommendation envisages the need for prior agreement to enable visas to be available for unannounced audits. It is likely this will not be straightforward for certain countries. Arrangements will favour Notified Bodies, such as SGS, which have local medical device auditors in many countries. Notified Bodies will also require undertakings from manufacturers on the security of the audit teams.

d). Contracts with predefined or fixed costs will have to be reviewed and amended, and it is likely that many costs will have to be open ended to cover the wider range of circumstances.

e). As some weaker Notified Bodies lose designation, or are restricted in scope, manufacturers may be contacted and informed that the certification contract will be unilaterally ended. Normally manufacturers will be allowed 6 to 12 months to find a replacement Notified Body.

PRIORITY ACTIONS FOR MANUFACTURERS

All of the following points should be considered in relation to the new legislation:

a). Manufacturers should review their control of all critical subcontractors and suppliers (including OEMs if the manufacturer is own brand labelling). Care must be taken to ensure that no legal responsibilities have been delegated and that control is adequate and risk based.

b). Manufacturers should ensure that they have good systems for informing their Notified Body of changes to product ranges, quality systems, critical suppliers and the design of high-risk devices.

c). Manufacturers should ensure that there are written procedures describing processes which will ensure compliance to regulatory requirements. This would include compilation and approval of technical documentation, EC declarations of conformity, vigilance, determination of class (etc.).

d). Manufacturers should ensure that they are aware of all relevant EU Commission documents including MEDDEVs and classification decisions and that the requirements are incorporated into the QMS and technical documentation.

e). Manufacturers urgently need written procedures for managing unannounced audits, although these are not a requirement to be audited.

f). Manufacturers should ensure that all technical documentation has been updated in line with current device design and manufacturing practice.

g). It is recommended that a check of production against technical documentation and a traceability audit be incorporated into the internal audit process.
h). Manufacturers should make a judgement whether their Notified Body is likely to find compliance with the new requirements difficult because of limited resources, low technical competence or low prices, and consider moving to a stronger Notified Body.

i). Manufacturers should be ready for all the new expectations and unannounced audits from the beginning of 2014.

j). Best practice for manufacturers would be to immediately review the Recommendation document and undertake an internal audit/gap review of processes and technical documentation to identify any areas of weakness and then to implement an improvement plan before the first Notified Body audit in 2014.

CONCLUSIONS

These two EU Commission documents do not represent new requirements for manufacturers only for Notified Bodies. Manufacturers who have been implementing best practice, following MEDDEV guidance and ensuring that classification and borderline decisions have been implemented have little to do other than institute a procedure to manage unannounced audits. However manufacturers who have fallen behind current best practice or who have chosen a lenient or incompetent Notified Body will have to review and improve processes and documentation or expect significant non conformities.

Notified Bodies who themselves have fallen behind best practice and who do not meet the new competency criteria will also have to review and improve processes or expect suspension or reductions in scope. As has been widely forecast the number of Notified Bodies will reduce significantly, and even before the full application of the Implementing Regulation several Notified Bodies have closed or been suspended during 2013.

SGS consider that they do utilise most current best practice and SGS-certified manufacturers will find the gap between previous and current expectations is less than for many of their competitors who have chosen Notified Bodies with lower levels of competence.

The two documents have no transition period so are effective immediately, although most Competent Authorities will accept that Notified Bodies will have to be given time to change contracts and implement arrangements for unannounced audits.

Most or all of the changes will be in place during the first quarter of 2014.

FURTHER INFORMATION

The EU Commission documents relating to this article are available in the Official Journal dated 25 September 2013.

Register for the upcoming webinar sessions about the topic on November 12 and 13, 2013 at SGS MD Webinars.
CURRENT EDITION: “MEDICAL DEVICES REGULATIONS IN THE MAIN GLOBAL MARKETS” WHITE PAPER

The document summarizes the main aspects of the medical device regulations that currently apply to the thirteen main global markets. The current edition contains the new regulations for Notified Bodies published by the European Commission at the end of September.

Click on the image to download the white paper.

NEW WEBINAR ABOUT THE CHANGES TO CE CERTIFICATION OF MEDICAL DEVICES

The webinar will explain the changes in auditing and technical file assessments for medical devices which will be starting in 2014. It will outline the main changes in the two EU Commission documents published on September 24 and help manufacturers plan their compliance and management of new features such as unannounced audits.

View webinar recording.