MEDICAL DEVICES NEWS
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EDITORIAL

Dear Reader,

We know compliance and speed to market in the medical devices industry relies on staying up to date on global and local regulations. The SGS Medical Devices Newsletter is your one-click stop for the latest information from around the world of medical devices.

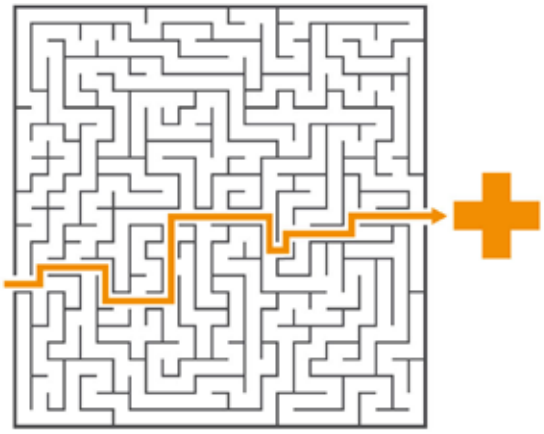
Within this issue, you will find the latest information on current MD developments, including:

- Chinese Medical Device Market
- SGS Exhibits at MEDICA 2014
- Sign-up to SGS Webinars and stay informed

If you have any comments or suggestions on this newsletter or for future content, please do get in touch via medicaldevices@sgs.com.

Best regards,

SGS Medical Devices Expert Team



GET YOUR MEDICAL DEVICES TO MARKET
FASTER WHEN YOU KNOW THE WAY

SPECIAL POINTS OF INTEREST:

SGS

CHINESE MEDICAL DEVICE MARKET

The Chinese medical device market is the fourth largest market in the world. The estimated market value was over 17 billion dollars in 2013 and the market is growing fast. Expected growth is 15-20% per year for the next 10 years, and with Chinese manufacturers not able to meet demand, it makes China an attractive market for foreign medical device companies. On 1 June 2014, the newly revised Regulations for the Supervision and Administration of Medical Devices' (State Council Order No.650) were put into force. To support the implementation of the regulations, the China Food and Drug Administration (CFDA) formulated and revised five important administrative measures. These administrative measures will go into effect on October 1, 2014.

CHINESE REGULATORY ENVIRONMENT FOR MEDICAL DEVICES

Approval from the China Food and Drug Administration (CFDA) is required for medical devices to be put into the Chinese market.

The most important laws and regulations for medical devices are:

The Council Statute Order No.650: 'The Regulations for the Supervision and Administration of Medical Devices' (enacted on 1 June 2014)

CFDA Order No.4: Administrative Measures for Medical Device Registration (will go into effect on 1 October 2014)

CFDA Order No.5: Administrative Measures for the Registration of In Vitro Diagnostic Reagents (will go into effect on 1 October 2014)

CFDA Order No.6: Administrative Rules for the Instructions and Labels of Medical Devices (will go into effect on 1 October 2014)

CFDA Order No.7: Administrative Measures for the Supervision of Medical Device Manufacturing (will go into effect on 1 October 2014)

CFDA Order No. 8: Administrative Measures for the Supervision of distribution of Medical Devices (will go into effect on 1 October 2014)

Harmonised GB National Standards and YY&YY/T standard (e.g. GB 9706.1:2007 – identical to IEC 60601-1 Ed.2 – and GB 16866 series – identical to ISO 10993 series)

MEDICAL DEVICE CLASSIFICATION AND TESTING

The CFDA has a similar classification for medical devices as the FDA: Class I devices are carried through routine administration, but Class II and III have stricter controls, accordingly. Provisions for classification are given in CFDA's Order 15 here.

(NB: To support the new regulations, the updated provisions for classification are in draft format.)

For Class II and III equipment testing, the manufacturer should draft the technical requirements. The requirements are similar to the Essential Requirements Checklist and should:

- Be in compliance with adopted standards (GB National standards and YY&YY/T industrial standards)
- Include performance specification and testing method

For active Class II and Class III devices, the CB test reports do not exempt them from testing, but they can be helpful. The devices will be tested according to the technical requirements in a Chinese testing laboratory that is supervised by the CFDA.

The applicable national standards are:

- For General Safety: GB 9706.1:2007 (identical to IEC 60601-1 Ed.2) is mandatory
- For Class II Devices: EMC testing YY0505:2012 (identical to IEC 60601-1-2:2004) is mandatory from 2015
- For Class III Devices: EMC testing YY0505:2012 (identical to IEC 60601-1-2:2004) is mandatory from 2014

CLINICAL REQUIREMENTS

For Class I, the supplied clinical evaluation report will be accepted.

For Class II and Class III device:

- If the device falls under 'clinical trial exemption database' the supplied clinical evaluation report will be accepted
- If the device does not fall under 'clinical trial exemption database' clinical trial in China is mandatory

(NB: The 'clinical trial exemption database' is still in draft format.)

CFDA APPLICATION AND REGISTRATION

The CFDA application and the required documents need to be provided in Chinese and in English. For the application and contacts, a Chinese Registration Agency is required – the manufacturer signs the English versions of documents, and the agency in China signs the Chinese versions.

In addition to the application, several other documents are required:

- Qualification for Manufacture: a certificate issued by the authorities (or Notified Body) of the Country of Origin (CoO) to authorise the manufacturer to manufacture and distribute the medical devices, for example in the EU this is an EN/ISO 13485 certificate
- Approval for the device in the CoO: for example in the EU this is the CE Certificate and Declaration of Conformity
- Qualification of Registration Agency: comprises the License of the Agency and an Authorisation Letter from the manufacturer
- Technical Requirements: typically drafted together with the manufacturer and the registration agency, and based on the user manuals, test reports and technical specifications
- Test Report for Class II and Class III devices: issued by the testing laboratory that is authorised by CFDA, based on the technical requirements
- User Manual and Labelling in Chinese
- Clinical Evaluation Report: (see the clinical requirements)
- Product Quality Guarantee Letter: with this letter the manufacturer guarantees that the quality of the product that is to be registered for sale in China is exactly the same in CoO, and that the quality management system is continuously supervised
- Letter of Authorisation and Letter of Promise for the Responsible Agency in China: the agency will need a business license, will undertake the relevant legal responsibility of product quality, report possible incidents to the CFDA, take care of product recalls, and contact the CFDA and manufacturer when necessary
- Letter of Authorisation and Letter of Promise for the After-sales Agency: the agency will need a business license and will have responsibility of all necessary technical documents, training, spare parts, consumables, and after-sales of the device
- Self-declaration for Documents Submitted: provided by the manufacturer and includes a promise from the manufacturer to undertake legal responsibility

(NB: To support the new regulations the document list above will be updated – no official notice of changes to date.)

In principle, the CFDA technical review and administrative review need 90 working days if there are no on-hold comments.

In practice, the expected lead-time for a Class II device is typically 9-16 months (e.g. documents preparation, testing, CFDA review).

FURTHER INFORMATION

SGS China can assist in scheduling the registration process, give an action plan for each step, provide guidance for the CFDA application and document preparation, and review the documents, communicate with the testing lab and follow-up the review process to ensure smooth progress. Additionally, SGS can give relevant CFDA registration regulation consultation.

For more information on SGS Medical Devices Services please visit www.sgs.com/medicaldevices or contact us directly at global.cgnr@sgs.com

SGS EXHIBITS AT MEDICA 2014 – NOVEMBER 12-15, DUSSELFDORF, GERMANY

SGS will participate as an exhibitor at MEDICA 2014, taking place in Dusseldorf, Germany, November 12- 15. Thanks to its strengthened position in the Medical Devices industry, SGS will present at MEDICA 2014 an expanded inspection, testing and certification service offering. In keeping with the previous years, SGS will participate as a co-exhibitor together with the Association of British Healthcare Industries in Hall 16, booth no. G10-5.

MEDICA 2014 - BIGGER AND BETTER

MEDICA is the world's premier trade fair for the medical sector, and it has attracted over 132,000 visitors from around 120 countries in 2013.

This is the venue that gathers all the latest innovations in the medical sector in one place. MEDICA 2014 is bound to continue the success of previous years, bringing together all the players in the global medical sector. With over 4600 exhibitors expected, there will be an overwhelming number of innovative products and services on display. A wide range of upstarts from around the world and all multinational heavyweights will present their latest products in 17 exhibition halls, covering 115,000m2. The event will continue to build on the success of its forums and conferences program, bringing back 2013's highly appreciated conferences on sports medicine, hospital management and disaster and military medicine. Furthermore, a wide range of events will continue to focus on the latest developments in medical tech, health IT, wireless, and wearable medical devices.

SGS BRINGS ITS TOP EXPERTS AND FULL SERVICE PORTFOLIO AT MEDICA 2014

The intense focus on electro-medical technologies at MEDICA 2013 translated also into a high level of interest in SGS's service portfolio, especially in the types of solutions that can ensure fast market access for new electro-medical devices. For MEDICA 2014 SGS has further strengthened its service offering and the depth of its expertise. Top experts from the SGS global network will attend the event, providing visitors direct access to our expanding medical devices service portfolio.

At MEDICA SGS will showcase an even wider range of medical devices testing and certification solutions, including for the new requirements stemming from ROHS II, and a comprehensive test report service that enables such reports to act as global safety passports when placing electro-medical devices on various markets around the world.

FURTHER INFORMATION

SGS is the world's leading inspection, verification, testing and certification company. At MEDICA 2014, and throughout the entire year, our global network allows our customers quick and direct access to SGS' broad range of medical devices services and testing facilities. Our services for electro-medical devices are available in all manufacturing regions and close to all major medical markets.

Regardless of your project's scope and target markets, SGS can improve the quality and efficiency of your electro-medical devices by combining in a one-stop package the advantages of worldwide reach, wide-ranging accreditations and multi-discipline expertise.

Visit us at our booth in Hall 16, booth no. G10-5.

Click here to make an appointment.

SIGN UP TO SGS WEBINARS AND STAY INFORMED

When developments in the medical devices industry require a more in-depth explanation – such as the changes that came into force in 2014 for auditing and technical file assessments in the EU – then sign up for SGS' complimentary one-hour webinars and stay informed. The SGS webinar (45-minute presentation/15-minute Q&A) on the main changes in two EU Commission documents published on 24 September 2013 helps manufacturers better plan compliance and management of new features such as unannounced audits.

WEBINAR SUMMARY

Changes in auditing and technical file assessments that affect medical device manufacturers or organisations requiring certification under the relevant EU directives (i.e. Active Implantable Medical Devices, 93/42/EEC Medical Devices, 98/79/EC In Vitro Diagnostic Medical Devices) are outlined in the webinar.

Topics include:

1. Introduction and Background
2. Changes to Audits and Quality Management Systems
3. Unannounced Audits
4. Changes to Technical Documentation and Technical File Assessments
5. Changes for Notified Bodies
6. Changes to Contracts
7. Priority Actions for Manufacturers

WEBINAR PRESENTER

Chris Jepson, SGS Global Manager Medical Devices, hosts the webinar and manages SGS' global medical devices activities. Chris is currently Chair of NB MED, the forum of Medical Device Notified Bodies, Industry, EC Commission and other interested parties. In this role, he is involved with the ongoing European discussions on changes to current Notified Body policy and the future revisions to the medical device directives. Chris is a chartered materials engineer and fellow of the Chartered Quality Institute.

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MEDICAL DEVICE REGULATIONS IN THE MAIN GLOBAL MARKETS

This white paper summarizes the main aspects of the medical device regulations that currently apply to the 13 main global markets (Australia, Brazil, Canada, China, Egypt, Europe, Hong Kong, Japan, Korea, Saudi Arabia, Singapore, Taiwan, USA).

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WHEN YOU NEED TO BE SURE

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