MEDICAL DEVICES NEWS
JUNE 2015, ISSUE 14

SPECIAL POINTS OF INTEREST:

EXPORTING MEDICAL DEVICES TO RUSSIA 2
OPTIMISING MARKET ACCESS IN BRAZIL WITH INMETRO 3
SGS ELECTRO MEDICAL DEVICES IN ATLANTA USA 5
EU DIRECTIVES AND CE MARKETING CASE STUDY 6
MEDICAL DEVICES WEBINARS 7
MEDICAL DEVICES WHITEPAPER AND SUBSCRIPTIONS 8
Medical devices destined for the Russian market must meet both national and regional regulations. This means demonstrating compliance both to Law 323 of the Russian Federation and the relevant Customs Union Technical Regulations (CU-TR).

Russia is an integral part of Eurasian Customs Union, which also includes Belarus and Kazakhstan. Medical devices are regulated by CU-TRs and must demonstrate compliance before they are imported and placed on the market.

RUSSIAN REGULATIONS
At the present time, compulsory requirements for medical devices are included in each member country’s national legislation. In Russia, this is implemented as article 38 of law number 323 of the Russian Federation. The law includes definitions of medical devices, classifications, risk classes and methods of registration.

Preparations for a new law on the Safety of Medical Devices are currently ongoing. The new law will include requirements for manufacturing, sales, marketing and use of medical devices. It will also define the responsibilities of all parties involved in their manufacture and distribution.

CUSTOMS UNION HARMONIZATION
At the Customs Union level, requirements for medical device safety, effectiveness and quality, is still a work in progress. Common requirements will cover, for example, toxicological, clinical and technical requirements, and testing. The intention is to harmonise requirements within the Customs Union with existing European requirements. How this will be realised is not defined at this stage.

ECONOMIC LIMITATIONS
In February 2015, the Russian government published Act 102. This new legislation places limitations on how the Russian state and communities may purchase foreign medical devices. These limitations are part of the country’s economic crisis recovery plan and cover about 40 different product categories, including CT and X-ray devices, ECG and blood transfusion equipment. The full list (in Russian) (PDF 170 KB).

FOR FURTHER INFORMATION:
Nina Pihlman
Russian and Customs Union Certification Operations Manager
SGS Finland
SGS Inspection Services Oy
Sarkiniementie 3 (P.O. Box 128)
FI-00210 Helsinki, Finland
t: +358 9 6963 666
OPTIMISING MARKET ACCESS IN BRAZIL WITH INMETRO

In an increasingly competitive market, organisations around the world are investing in optimisation and continuous improvement of their operations in order to surpass the competition. Medical devices distributed and/or sold in Brazil must comply with regulations from the National Health Surveillance Agency (ANVISA) and the National Institute of Metrology, Quality and Technology (INMETRO).

SGS gives organisations the ability to achieve these twin goals of optimisation and continuous improvement. As one of the world’s leading inspection, verification and certification companies, SGS is an accredited Certifier in Brazil, appointed by the General Coordination for Accreditation of INMETRO (CGCRE). In addition to our global expertise, we also work with local resources to deliver all support and services needed by medical device manufacturers and importers.

In Brazil, certification is one of the requirements considered before products can be granted registration for commercialisation by ANVISA. CGCRE accredited bodies can complete product assessment and award certification, and the right to display the INMETRO mark. Certified products must then display the INMETRO mark. It is mandatory and is a guarantee that a product meets the country’s quality, safety and efficacy requirements.

It is important to know that the certification process is intended primarily to inform and protect consumers, particularly with regard to health, safety and the environment. In addition, product certification seeks to promote fair competition between manufacturers and encourage continuous quality improvements in products. Globally, certification provides adequate controls with regard to international trade, while at the same time strengthening Brazil’s internal market.

HOW DOES ANVISA DEFINE MEDICAL DEVICES?

Resolution RDC Nr 27 issued by ANVISA on 21 June 2011 – defines that the equipment (including parts and accessories) under sanitary surveillance are those for medical, dental, laboratory, or physiotherapeutic purposes, used directly or indirectly for diagnosis, treatment, rehabilitation and monitoring of human beings, as well as equipment for beauty and aesthetic purposes. Another rule that must be considered in deciding whether or not a product needs certification is Normative Instruction Nr 11, issued by ANVISA on 16 December 2014. This rule brings together all the standards that must be considered to state whether the product is eligible or not for certification, and also the deadline for the cases where the certification is not yet mandatory.

Nevertheless, manufacturers can share this task with an Organisation of Certification of Product (OCP), such as SGS. We are accredited as an OCP by CGCRE (the Brazilian Authority for accreditation of product certification bodies) to issue certificates. We can also issue declarations to confirm that a product does not fall within the scope of the certification scheme.

Below are some examples of products for which certification is mandatory:
- Diagnostic equipment
- Therapy equipment
- Medical-hospital support equipment
- Disposable materials and devices
- Medical-hospital support materials and devices
- In-vitro diagnostic products (certification process not mandatory)
- Beauty and aesthetics devices
- Motorised wheelchairs

It is worth noting that ultimately, ANVISA defines exclusions from CGCRE certification.

HOW DOES THE CERTIFICATION PROCESS WORKS?

Regulatory compliance

It is important to remember that medical devices intended for sale in Brazil must have prior approval from ANVISA. ANVISA has developed a set of essential requirements for medical device compliance, which gives two routes to ANVISA approval: cadastre and registration. Cadastre is the simpler and faster option for lower-risk devices, but both Cadastre and Registration require similar documentation.

The approval process is completed via a GMP audit that is performed directly by ANVISA. This must be done before the registration submission, because for some products a GMP certificate is a pre-requisite. Therefore, it is necessary to first classify the class of risk of the product for registration to determine whether or not a GMP certificate/audit will be required.
CGCRE CERTIFICATION PROCESS

Medical devices covered by any standard included in the Normative Instruction Nr 11, considering the evaluation deadline, must be certified by an OCP and display the INMETRO mark.

The certificate demonstrates the quality of a system, process, product or service, through an examination and review of compliance with specified requirements, technical standards and technical regulations. All processes are defined in ORD 350, issued by INMETRO on 6 September 2010. The current evaluation mechanism used by OCPs to issue the compliance certificate can be summarised in the following steps:

- Initial assessment: the applicant submits to the OCP a formal request for the product that will be certified, with the minimum documentation required
- Initial factory inspection focusing on ISO 13485 clauses and routine tests, in accordance with clauses 18, 19 an 20 of IEC 60601-1 and conducted on 100% of products bearing the INMETRO mark
- Test reports must be issued by laboratories accredited by members of ILAC, IAAC or EA according to all applicable IEC standards. These reports must be issued no more than 2 years old, considering the date of initial certification process, and must be redone in the renewal
- Annual factory inspections to maintain certification
- Initial SAC inspection focusing on whether the Brazilian Representative is in compliance with the requirements of ORD 350 (customer complaints, traceability control of the products bearing the compliance seal, etc.)

Brazil uses international standards to guide their rules, however, these are always adapted to meet local requirements. Transition to the third edition of the IEC 60601-x series of standards, requires extensive commitment from all sectors involved. It was expected that from January 2014 the third edition would be mandatory, but it happened only partially. Currently, Brazilian laboratories hold accreditation to test against some, but not yet all, IEC 60601 third edition standards. Although ANVISA’s Normative Instruction IN 11 includes some deadlines to consider, for example the third edition standards becoming mandatory, test reports according to the standards in the second edition will be accepted until Brazilian laboratories are fully accredited to complete the relevant tests for all standards listed on IN11. It should be remembered that the requirements of ORD 350 are under review. This includes harmonisation with the third edition of the IEC 60601 standards and extensive impacts on documentary analysis and factory inspection.

IMPORT CONTROLS

Customs agents check medical devices transported to Brazil against the ANVISA database, to ensure they comply with registration requirements, before they are allowed to enter the country.

MONITORING CERTIFICATION

Continuity of medical electrical equipment certification, and authorisation for continued use of the certification mark, are based on results of the annual audits of the factory and importer/distributor. Audits are conducted to ensure continued compliance of the product and process, before the certification scheme requirements are established. In addition, during the five years of validity of the certificate, any design changes to a certified product must be reported and approved in advance by the OCP before deployment.

LOCAL REPRESENTATION

To sell your products in Brazil you must not only meet the ANIVSA approval requirements, but also have a representative within the country that can act on your behalf in all product-related matters.

WHY CHOOSE SGS?

SGS is the world’s leading inspection, verification, testing and certification company. We are recognised as the global benchmark for quality and integrity. With more than 80,000 employees, we operate a network of more than 1,650 offices and laboratories around the world. SGS operates a national and international network of accredited laboratories. Coupled with more than 70 years working in Brazil, our expertise in electrical and electronic products classed as medical devices, makes SGS the partner to trust.

Independent and innovative, our medical devices experts use state-of-the-art facilities and technology to deliver tailor made added value services that help improve your business.

We strive to deliver outstanding value at every step in your project by providing:

- Rapid turnaround
- Value-based pricing
- Technical assistance
- Key account management

Our expertise in compliance management will help you make the right choices for different national markets, while carrying out the necessary testing and certification quickly and professionally.

FOR FURTHER INFORMATION:

To learn more about SGS’s CGCRE certification services contact your local SGS representative, or contact our global team or visit SGS Medical Devices website.
SGS ELECTRO MEDICAL DEVICE SERVICES IN ATLANTA, USA

SGS’s Atlanta lab was founded in 1880 as the US Testing Company and became part of the SGS Group in 1963. Today the lab serves the following key competences for electro medical devices:

- Product safety
- Electromagnetic compatibility (EMC)
- Wireless testing & certification
- Battery Testing

Established: 1963
Employees: 40

Laboratory Features
This lab serves as the gateway for electro medical device services in the USA and Canada. Furthermore, the facility incorporates test and simulation labs covering an area of more than 2,600m². Accreditations and approvals received by this facility include:

- ISO/IEC 17025, ISO/IEC 17065
- Notified Body for EMC and R&TTE Directives
- IECEE CB Scheme
- US OSHA NRTL
- Standards Council of Canada (SCC) testing & certification organisation
- Field Inspection Body for onsite inspection of medical devices

Key Services
- EMC testing e.g. IEC EN 61326, IEC EN 60601-1-2 (10m chamber, 3m chamber)
- Product safety testing e.g. IEC EN 60601-x Series, IEC EN 61010-x Series
- Environmental simulation testing
- RoHS & WEEE
- Notified body (NB) and quality management systems (QMS) ISO 9001, ISO 13485, CE 0120, CE 0598
- Stability testing of packages and materials

Our technical team has experts in all electro medical device testing services, for example HF surgical products, as well as all other services needed for product safety.

Quality Marks
The SGS Atlanta lab offers a wide range of marks to help you gain access to the global marketplace:

- USA NRTL (AAMI & UL Standards), SGS US/C certification mark
- USA Test Reports as part of a FDA 510(k) or PMA, FCC
- Canada (CSA Standards)
- Europe (CE, EN Standards)
- Brazil (INMETRO)
- CB (Global, IEC Standards)
- SGS Fimko, SGS CEBEC

For Further Information:
Mark Tavano
Account Executive, Electrical & Electronics
SGS North America, Inc.
620 Old Peachtree Road
Suite 100
Suwanee, Georgia
United States
t: +1 973 349 5484
EU DIRECTIVES AND CE MARKETING CASE STUDY

This complimentary Webinar provides an overview of the three European Medical Device Directives and explains the process for obtaining a CE Mark. The presentation provides an overview of the associated guidance documents. The example of a low-profile, spinal pedicle screw is used as a case study example in this presentation. The case study explains how to determine the proper classification and to document the rationale for that classification. Milestones in the process for obtaining a CE Certificate are also explained.

PRESENTERS:

Rob Packard, Medical Device Academy, Inc.

The speaker has 20+ years experience in the medical device, pharmaceutical and biotechnology industries. He is a graduate of UConn in Chemical Engineering with Quality Management System expertise covering all aspects of developing, training, implementing and maintaining compliance with ISO 13485 and ISO 14971. From 2009-2012, he was a lead auditor and instructor for a Notified Body. Rob’s specialty is regulatory submissions of high-risk medical devices for CE marking, Canadian medical device applications and 510(k) submissions. He founded the Medical Device Academy in 2012 as a consulting firm focused on helping medical device companies with regulatory submissions and quality system implementation. The most favorite part of his job is training others.

Mick Howk, RAC, CQE, CQA
SGS Regional Manager - Healthcare

Mick holds over twenty years’ experience in quality assurance and regulatory affairs. His experience includes over ten years working directly with European Notified Bodies assisting clients seeking global medical device approvals. He has successfully implemented and maintained ISO compliant quality systems resulting in certification. Mick has worked with companies seeking CE Marking under the MDD, IVDD and AIMD including startup companies as well as global corporations seeking to consolidate certifications. Mick has provided training to hundreds of employees on a broad spectrum of quality and regulatory topics. Mick holds a Master’s Degree in Management and a Bachelor’s Degree in Industrial Engineering Technology as well as numerous industry certifications in quality and regulatory.

Register to watch the webinar.
MEDICAL DEVICES WEBINARS

CMDCAS CERTIFICATION AND THE CANADIAN MDR

This webinar provides an overview of the Canadian Medical Devices Regulations (CMDR) and explains the process for CMDCAS Certification. Our speaker identifies each of the unique requirements that differentiate CMDCAS from standard ISO 13485 certification. He also provides advice on how to organize your technical documentation to simultaneously meet the requirements of Health Canada and the future European Medical Device Regulations.

Topics include:
- Organization of the CMDR
- Mandatory Problem Reporting
- Recalls
- Distribution Records
- Medical Device Licenses
- Establishment Licenses

PRESENTERS:
Rob Packard,
Medical Device Academy, Inc.

The speaker has 20+ years experience in the medical device, pharmaceutical and biotechnology industries. He is a graduate of UConn in Chemical Engineering with Quality Management System expertise covering all aspects of developing, training, implementing and maintaining compliance with ISO 13485 and ISO 14971. From 2009-2012, he was a lead auditor and instructor for a Notified Body. Rob’s specialty is regulatory submissions of high-risk medical devices for CE marking, Canadian medical device applications and 510(k) submissions. He founded the Medical Device Academy in 2012 as a consulting firm focused on helping medical device companies with regulatory submissions and quality system implementation. The most favorite part of his job is training others.

Ron. M. Mathis
Mr. Mathis is SGS’s VP for Healthcare. In this role, he is responsible for the leadership of the Healthcare section, including Medical Device Certification and Training, as well as the delivery of auditing service within the Pharmaceutical and Cosmetics Industry for SGS in North America. An industry veteran with many years of experience in Management Systems, Ron’s experience include leadership roles in other certification Bodies.

Please see archived link below to view this webinar:
CMDCAS Certification and the Canadian MDR

EVALUATING CRITICAL SUPPLIERS

Critical suppliers include subcontractors that perform high-risk processes, such as the manufacture of finished devices or major device components, special processes, calibration houses, test houses, contract sterilization, or contract packaging. Both FDA QSR and EN ISO13485 and IMDRF guidance spell out some of the elements for control over critical suppliers, including the requirements for the manufacturer’s purchasing and production/service processes, best handshake practices with individual suppliers, and contractual agreements. This makes it necessary for a manufacturer to select suppliers wisely to ensure that the critical supplier can help meet regulatory requirements and remain a partner for an extended timeframe.

The webinar is aimed at providing quality management, procurement, financial and operations professionals with additional insights into a risk-based approach to identifying, evaluating, and controlling critical suppliers.

Topics include:
- Initial assessment, evaluation and selection of critical suppliers
- Ongoing assessment of critical suppliers
- Transition to new critical suppliers

PRESENTERS:
Joyce Ludwig
M Squared Associates

The speaker has 30 years of experience in Quality Management Systems for both domestic and global implantable medical device organizations. Her unique perspective of partnering with suppliers has transformed the “low bid approach” into “quality initiatives” and creating stable, value-added, synergistic relationships with key critical suppliers. Joining with procurement, financial and operations departments to jointly review initial assessments of critical suppliers provides consensus into decision making for selecting critical suppliers.

Ron. M. Mathis
Mr. Mathis is SGS’s VP for Healthcare. In this role, he is responsible for the leadership of the Healthcare section, including Medical Device Certification and Training, as well as the delivery of auditing service within the Pharmaceutical and Cosmetics Industry for SGS in North America. An industry veteran with many years of experience in Management Systems, Ron’s experience include leadership roles in other certification Bodies.

Please see archived link below to view this webinar:
Evaluating Critical Suppliers
MEDICAL DEVICES WHITE PAPER

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

WATCH Medical Devices Webinars

Stay informed with webinars covering topics on 2014 changes for auditing and technical file assessments in the EU, Clinical Evaluation, and more.

FOLLOW SGS ON LINKEDIN

Optimize your development timelines to get medicines and medical devices to market quickly and safely, utilizing SGS expertise and resources to navigate the complexities of the Life Science industry.

ONLINE SUBSCRIPTIONS

Subscribe or manage your information with a click.

THE MEDICAL DEVICES NEWSLETTER ARCHIVE

Go back to previous issues for your reference.