South Korea facilitates approval
Changes for Medical Devices in classes I and II, IVDs and third-party testing

The Korea Food and Drug Administration (KFDA), a government agency of the Ministry of Health and Welfare (MOHW), has regulated the South Korean health market since 1997. The basis for the approval of Medical Devices is the Medical Device Act (MDA) which lays down comprehensive requirements concerning their safety and effectiveness. The KFDA controls MDA implementation with the help of detailed regulations and directives governing technical requirements, test procedures and processes. 2011 and 2012 saw wide-ranging new regulations come into effect which makes approval easier for a large number of Medical Devices.

The approval process in South Korea in brief
All suppliers who want to become active on the health market in South Korea must be approved by the KFDA. Foreign companies not located in South Korea cannot enter the South Korean market directly or submit applications for the approval of Medical Devices there. Given this, they need to appoint an importer license holder in South Korea.

Simple notification in class I
In step one of the approval process, Medical Devices are categorized under one of four risk classes which are subject to different approval requirements. Devices in class I only need to be registered via the online notification system of KFDA. The KFDA reviews the documentation of the Medical Devices and supplies an online certificate of Medical Device notification. Devices in classes II to IV require KFDA approval.

Dear Readers,

“Desire to have things done quickly prevents them from being done thoroughly. Looking at small advantages prevents great affairs from being accomplished.”
Around 2,500 years ago, China’s most famous philosopher Confucius adeptly summarized what today is still the quintessence of human coexistence, as well as the core of business life in general and of our work with colleagues and authorities in Asia. Personally, as a European I had the pleasure of spending more than six years in Japan and Singapore, where I came to appreciate the Asian virtues. Given this, I am delighted to present you news from as many as three Asian countries in this newsletter: the focus is on South Korea, one of the most popular import markets in the world. Japan recently published a revision of its national standard JIS T 0801-1, while in Malaysia the new Medical Device Act (MDA) came into effect in October 2012.

However, we can also report news from other areas. For example, we provide you with an overview of the transition periods of the IEC 60601-1 in various target markets. Or are you already familiar with our Med-Infos, our regular information bulletins for the Medical Device industry? In addition to the customary PDF format, they are now also available as e-books for your mobile devices.

I hope you find our newsletter an interesting and informative read.

Best regards,
Dr. Peter Havel
Senior Vice President, Medical & Health Services Global

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Technical documentation for devices in class II and higher
The heart of the application for approval is the technical documentation. For most of class II Medical Devices, general technical documentation must be reviewed.

For class II Medical Devices with at least three equivalents already approved on the South Korean market, technical documentation review is waived. In this case, equivalency has to be verified in intended use, operation principle and used materials, performance, test specification and operation methods etc. by a KFDA-registered laboratory.

In cases involving new types of devices, a new technology, a new intended use for a class II device or devices in classes III and IV, the KFDA requires submission for a Safety and Efficacy Review (SER) – Technical File plus clinical studies.

The technical documentation of class II Medical Devices is reviewed by a KFDA-approved third-party organization. All other cases are reviewed directly by the KFDA.

Test reports for Medical Devices in class II and higher
For Medical Devices in class II and higher, test reports on the function, safety and efficacy issued by KFDA-approved laboratories must be enclosed with all applications for approval. Own function tests carried out by manufacturers that underwent a KGMP (Korean Good Manufacturing Practice) compliance audit are accepted.

(Korean) Good Manufacturing Practice Audit
Medical Devices in classes II, III and IV and class I Medical Devices with sterile or measuring function additionally require a (K)GMP compliance audit. GMP certificates are valid for three years, while company and product approvals are valid for an unlimited period of time as long as the product is not modified.

Changes in the approval procedure 2011/12
1) Regulations merged
In April 2012, the separate regulations that governed review of the technical documentation and approval were merged into a single regulation also including IVDs (in-vitro diagnostics) (KFDA Notification No. 2012-8). Within the KFDA, an In-Vitro Diagnostic Medical Devices Task Force was set up.

2) Review by third parties now possible for the first time
In the past, the KFDA itself reviewed approval for all classes. Since February 2011, KFDA-appointed third-party organizations have been able to carry out review for class II Medical Devices.

As in the past, review of the technical documentation of IVDs, new class II Medical Devices and all Medical Devices in classes III and IV for which clinical study reports must be submitted are still carried out by the KFDA.

3) External test reports accepted
Test reports issued by external laboratories have already been accepted since February 2011, provided they are in compliance with KOLAS (Korean Laboratory Accreditation Scheme, ISO 17025) and issued as CB or GLP Reports. Own tests carried out by KGMP-certified manufacturers are also accepted.

4) GMP audits made easier
With effect from April 8, 2012, the GMP (Good Manufacturing Practice) audit is only required for 25 categories (formerly 39). The audit has been waived in cases involving minor changes to the product or class I Medical Devices, with the exception of Medical Devices with sterile or measuring function. For foreign manufacturers, an on-site GMP audit will be introduced in a step-by-step approach. Starting with class IV devices in 2012, the audit will then also become mandatory in 2013 for devices in class III, and in 2014 for class I and II Medical Devices with a measuring or sterile function. In the case of several production facilities, the site of the on-site audit is selected on the basis of criteria including risk, import volume, PMS data etc. The GIP audit for importers is dropped. (KFDA Notification No. 2012-12)

5) IVD Reagents are now partly regulated under Medical Device scheme
IVD reagents to be used with IVD instruments – which have not been regulated for pre-market approval – are now regulated as Medical Devices. They are classified under four classes. Product approval is required step by step from 2012 for class IV, and will be mandatory for all classes in 2014. Technical documentation review and GMP audit are required for approval. Technical documentation will be reviewed by KFDA directly.

Entering the South Korean market
From the manufacturers’ perspective, the access to South Korea’s medical device market is relatively transparent and reasonable. Nevertheless, foreign companies in particular face some administrative, cultural and language barriers.

In a country where saying “no” is considered impolite and where people are partial to flowery language, cooperation with the authorities also differs from our familiar EU bureaucracy. The fact that applications for approval must be in Korean does not make matters easier. In addition, not all new regulations are also published in English. Leaving approval solely in the hands of the Korean sales partner is a doubtful approach, since the application is critical for marketing products later on. Manufacturers who wish to keep control despite the language barrier are advised to take on board an impartial third party.

Support by TÜV SÜD Korea
TÜV SÜD has operated in Korea since 1992, maintaining offices in Seoul and Busan and a testing laboratory in Guro, Seoul. The company currently employs roughly 250 specialists in Medical and Health Services. Based on their abundant experience and in-depth knowledge of the requirements applicable on the South Korean Market, the experts support manufacturers in securing the necessary approvals. In addition to this, TÜV SÜD Korea is recognized by the KFDA as a third-party organization for the review of technical documentation of all product categories in class II.

You can find the website of TÜV SÜD Korea here.
Web links:
You can find the introduction to the approval of Medical Devices in Korea here.
The KFDA information portal in English is available here.

Current versions and directives:
Regulations:
Korean
English
Note: The English versions are not always up to date.

Directives:
Korean

Favorable indicators for the health market
The term “Miracle on the Han River” is used by an amazed world to describe the breathtaking economic growth that South Korea has experienced since 1954. South Korea is the only country in the world that has raised its national income 380-fold and its gross domestic product 750-fold in a mere 50 years – and that following a highly destructive war. Today, South Korea is one of the world’s leading economic nations, ranking 15th in the world by nominal gross domestic product. The country’s population is approaching the 50-million mark but is ageing rapidly. Since 2005, the average age of the population has risen from 34.5 to 38.4 years. Improvement of medical care is one of the declared objectives of the Korean government. South Korea already has the highest health spending of the four “Asian Tigers” (Hong Kong, Singapore, South Korea, Taiwan), and a further rise is expected over the next years. 55% of health expenditure is publicly financed.

Import dominates the Medical Devices market
South Korea is one of the most attractive export markets for the German Medical Devices industry. In 2008, the Medical Devices market already had an overall volume of USD 2.4 million – and it is still rising. In 2011, in Korea 2,899 new Medical Devices were approved, a year-on-year increase of 8.7 % compared to 2010; the top 3 were hearing aids (6.7%), tooth implants (3.8%) and soft contact lenses (2.5%). 51% of the new Medical Devices approved were imports. In general, European companies play a significant role in South Korea. The EU is the second biggest trading partner of South Korea after China, and the largest part of foreign investments is from the EU. Among the leading importing countries, Germany ranks second after the USA and before Japan.

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Manufacturers wishing to sell their Medical Devices on the Japanese market must prove by May 31, 2017 at the latest that their products are in compliance with the Japanese industrial standard JIS T 0601-1:2012. The 2012 revision of JIS T 0601-1 was published only recently. Now, the Japanese Ministry of Health, Labor and Welfare, MHLW, has defined a five-year transition period for its implementation. In parallel, TÜV SÜD Japan opened a new laboratory where the safety tests required by the JIS T 0601-1:2012 standard can be carried out in the future.

Testing in accordance with JIS T 0601-1:2012
TÜV SÜD Japan has already prepared for the new requirements and, parallel to the publication of JIS T 0601-1:2012 in Tokyo, has opened a new testing laboratory where it will conduct safety and function tests in accordance with the current requirements in the future. This includes tests related to electrical safety, safe earthing, power loss, requirements related to the power source and air and creepage distances.

The safety standard JIS T 0601-1:2012
The Japanese standard JIS T 0601-1:2012, with the full title “Medical electrical equipment – Part 1: General requirements for basic safety and essential performance”, refers to the safety and function of medical electrical equipment and corresponds to the European standard IEC 60601-1:2005, 3rd edition. The standard is one in a series of provisions which, in accordance with the Japanese Pharmaceutical Affairs Law, J-PAL, represent the requirements for approval in the Japanese market.

Transition by 2017
JIS T 0601-1:2012 applies to all manufacturers of medical electrical equipment, not only those of international origin. Until the end of the transition period in 2017, all manufacturers can apply for Japanese market approval in accordance with the JIS T 0601-1:1999 standard valid so far or the new JIS T 0601-1:2012 standard. However, manufacturers who wish to sell their products beyond May 31, 2017 must ensure that their devices will be in conformance with the revised standard by then.
One year ago, the Malaysian government introduced legal regulations governing approval on the Medical Device market. The Medical Device Act of October 3, 2011 is considered a milestone in healthcare, defining the requirements for the licensing of companies and the safety and function of technical Medical Devices. The new Act came into effect in October 2012, finally providing the Medical Device industry with a clear picture of the requirements they will have to meet in the future.

**Act No. 737: approval of companies and devices**
The Medical Device Act comprises two laws. Act No. 737, also referred to as the “Medical Device Act of 2012”, includes the requirements governing the conditions and prohibitions for the sale of Medical Devices. All companies, including manufacturers, importers, authorized representatives and distributors, must first obtain a market license. In the future, all Medical Devices – including bandages and dressings, condoms and syringes but also high-tech equipment such as magnetic resonance tomographs – will have to be approved by a Conformity Assessment Body, CAB. The act provides for risk-based classification and registration and establishes safety- and function-related requirements. In addition, Act No. 737 governs CAB approval.

**Act No. 738: Regulation by the Medical Device Authority**
Act No. 738, also referred to as the “Medical Device Authority Act of 2012” and published parallel to Act No. 737, defines that the Medical Device Authority (MDA) will be in charge of monitoring the implementation of the new requirements. The organizational structure and responsibilities of the MDA are comparable to that of the FDA in the United States, the corresponding regulatory authorities in the EU or the TGA in Australia. The MDA will take all measures that are necessary to implement the Act, regulates approval, develops specific regulations governing the pre-marketing, placement on market and post-marketing of Medical Devices, and monitors compliance therewith.

**Short transition periods up to 2013/14**
The Medical Device Act became effective in October 2012. The Act will presumably grant a two-year transition period for the approval of devices, up to October 2014. Manufacturers importing or placing on the market unapproved Medical Devices after this date will face severe fines of up to MYR 200,000 (around USD 64,000). Plans provide for the licensing of the companies to be completed one year earlier, in October 2013.

**The Medical Device market in Malaysia**
The new Medical Device Act is an important milestone in Malaysia’s development, which is striving to obtain the status of a fully developed industrialized country by 2020. Given this, the parliament of Malaysia has made an important step towards improving the country’s healthcare and expanding its healthcare system. The Medical Device Act is expected, among other things, to remove low-quality products from the market and strengthen quality-aware suppliers. Malaysia’s health spending amounted to an estimated USD 10.3 billion in 2010, and market analysts expect this figure to rise to around USD 19.0 billion by 2015. The five ASEAN countries — Malaysia, Thailand, Indonesia, the Philippines and Singapore — spend almost 10% of their annual health budget on Medical Devices and equipment. The annual sales revenue of Malaysia’s Medical Device market reached USD 1.3 million.

**Gain approval with TÜV SÜD Malaysia**
TÜV SÜD Malaysia applied for approval as Conformity Assessment Body (CAB) with the Medical Device Authority and has already been included in the list of assessment bodies. As soon as approval becomes official, TÜV SÜD can offer all conformity assessments in accordance with the new Medical Device Act No. 737. TÜV SÜD also offers audits for company approval in accordance with the ISO 13485 standard for manufacturers and in accordance with the “Malaysia Good Distribution Practice of Medical Device” (GDPMMD) for importers, authorized representatives and distributors.

The information by the Malaysian Health Ministry is available [here](#).

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3rd edition IEC/EN 60601-1
When and where the 3rd edition will come into effect – a global overview

For the manufacturers of Medical Devices, knowing when the 3rd edition of the IEC 60601-1 standard will come to replace the 2nd edition in the individual target markets is important as it concerns both the development and certification of their products. To provide you with a quick and compact overview, we have prepared a list of the various transition periods that apply worldwide.

<table>
<thead>
<tr>
<th>Region/country</th>
<th>Effective (today)</th>
<th>Acceptance of 3rd edition</th>
<th>Transition period</th>
<th>Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>2nd Ed. 3rd Ed.</td>
<td>Yes</td>
<td>The transition period for Medical Devices without an applicable part 2 standard expired on June 1, 2012. Applicable part 2 standards can change the transition period in both directions. Example: The transition period for ultrasonic equipment in accordance with the EN 60601-2-37:2008 standard already expired on October 1, 2010. However, the transition period for interventional X-ray systems in accordance with EN 60601-2-43:2010 will not expire until June 1, 2013.</td>
<td><a href="http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm">http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm</a></td>
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<tr>
<td>IECEE – CB scheme</td>
<td>2nd Ed. 3rd Ed.</td>
<td>Yes</td>
<td>No specific date known. Several years expected.</td>
<td><a href="http://dom5.iec.ch/ieecemembers.nsf/IECEEScopeInStandardByCat?ReadForm&amp;PC=MED">http://dom5.iec.ch/ieecemembers.nsf/IECEEScopeInStandardByCat?ReadForm&amp;PC=MED</a></td>
</tr>
</tbody>
</table>

* The table only includes data that have been officially confirmed.
In the European Union, the use of harmonized standards is recommended, but is not absolutely necessary to furnish evidence of compliance with the Essential Requirements (ER). According to the Medical Device Directive, the following transition periods have been defined for the EN 60601-1 standard:

a) For medical electrical equipment (MEE) without applicable part 2 standard until June 1, 2012

b) For MEE with applicable part 2 standard until the date defined in the EN part 2 standard. For example: EN 60601-2-37:2008 establishes that the transition period ends on October 1, 2010.

In this context, please note that EN ISO 80601-2-XX, EN IEC 80601-2-XX and any EN ISO XXXXX such as EN ISO 15004-1:2009, which are listed in the Official Journal of the European Union, and are based on the 3rd edition of EN 60601-1:2006, i.e. IEC 60601-1:2005 will be treated as part 2 standards. Consequently, their transition period will also change.

The following problems may arise when the transition period has already expired:

- Medical Devices approved in accordance with the 2nd edition can no longer be placed on the European market unless manufacturers can furnish impartial evidence that their devices are in compliance with the essential requirements of the MDD 93/42/EEC. The assumption of compliance with the essential requirements is based on the use of valid harmonized standards, in this case the 3rd edition. Given this, delta testing and assessment (2Ed → 3Ed) will be required.

Further information on this issue is available in ZLG-Papier 3.5 A1.

- Many manufacturers of Medical Devices are anticipated to require delta testing and assessment at the same time. This may lead to long waiting times in testing laboratories. Given this, we recommend that manufacturers contact TÜV SÜD Product Service, which is a Notified Body (NB), Certification Body Test Laboratory (CBTL) and Nationally Recognized Test Laboratory (NRTL), at an early stage in the process.

Further information about the transition from 2nd to 3rd edition within the scope of CE marking can be found here.
Med-Infos now also available as e-books
From November onwards, up to date information on the go

From November 2012 onwards, TÜV SÜD’s most important Med-Infos will be available in epub format in addition to pdf format. Users can thus read the texts on all iOS and Android mobile devices at any time. In contrast to pdf-files, the new format allows digital publication text to reflow according to screen size and adapt dynamically to the individual settings of e-book reader apps. Given this, the specialist information newsletter can now also be optimally displayed on smartphones and tablet devices.

In their Med-Infos, TÜV SÜD’s experts summarize current and relevant information from the following categories: “Standards & EU Guidelines”, “Clinical Affairs”, “International Affairs” and “Further Services.” At present, 33 Med-Infos are available on a wide variety of subjects, such as “Introduction to Korean Medical Device Regulations”. The specialist information newsletters are free and updated at regular intervals; they can be downloaded from www.tuev-sued.de/medinfo – effective this November both as pdf-files and epub-files.

As a special service for MEDICA visitors, between November 14 and 17, 2012 you can conveniently download all Med-Infos available in epub format to your smartphone or tablet computer at the TÜV SÜD stand by scanning in the QR code.

The following Med-Infos will be available as epub version from November on:

**Standards & EU Guidelines**
- IVD Directive 98/79/EC
- IEC 60601-1:2005: 3rd Edition
- Usability of Medical Devices

**International Affairs**
- Globalization of Medical Device Approval
- FDA 510(k)
- Access USA and Canada
- Access Russian Federation (GOST)
- Access Australia
- Chinese Approval for MD

**Further Services**
- Medical Device Software
Detailed checklists support manufacturers in the certification of sterile and reprocessable Medical Devices. Using these checklists as a basis, manufacturers can prepare for the certification of their Medical Devices in a well-structured and efficient manner and check the completeness of their documentation point by point. The “Submission Forms” thus ensure maximum transparency, saving manufacturers time and money.

Certification requirements in a nutshell
TÜV SÜD’s experts prepared lists for five areas and presented the various applicable requirements in easy-to-understand questions. The experts took great care to keep the individual questions as simple as possible. Manufacturers that require more in-depth information will find a reference to the relevant section of the related harmonized standard in the same line.

Manufacturers can enter the required evidence (section data) and references to the related sources of information (including name and page of the document) directly in the checklist. By adopting this approach, they gain a good overview of the certification process and can quickly review the required data for completeness.

The Submission Forms point out, for example, that full documentation of the completed test cycles is required and must be prepared. Manufacturers must also describe the validation of their microbial methods and provide the maximum microbial count up to which the sterilization process can still be commenced.

Submission Forms are available in the following areas:
- EO sterilization
- Radiation sterilization
- Steam sterilization
- Design of sterile packaging and validation of the packaging process
- Reprocessing of Medical Devices

Many advantages for manufacturers
The Submission Forms have a clear layout providing simple and complete technical documentation for large and small manufacturers of Medical Devices. This is an important aspect, as missing data result in lengthy and costly certification procedures. The Submission Forms supply manufacturers with an overview of all data, saving time and money.

The completed checklists not only support preparation for the certification procedure, but are also useful for internal evaluation and documentation: thanks to the simple structure of the data, overlapping certification requirements become evident at first sight, permitting manufacturers to use the already available data. Duplication of data entry thus becomes a thing of the past.

The use of these checklists is not mandatory but an optional service provided by TÜV SÜD for a simple and transparent certification process.

Order information
The Submission Forms can be ordered from Dr. Jan Havel, for a one-time fee of EUR 3,000 per Submission List.

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MEDDEV 2.1/6: software
Apps and stand-alone software: when is software a Medical Device?

Is a medical app enough to turn a smartphone into a Medical Device? This and other questions related to the classification of stand-alone software are broadly discussed within the scope of the Medical Device Directive (MDD) 93/42/EC, which is very vague in many of these areas. The new guidance MEDDEV 2.1/6 issued by the European Commission provides more clarity, supplying additional criteria, decision diagrams and numerous practical examples.

MEDDEV 2.1/6 now provides manufacturers and notified bodies with initial further assistance for the classification of stand-alone software as non-binding guidance. After all, the correct classification of products is one of the obligations for manufacturers.

MEDDEV 2.1/6 includes two decision diagrams from which users can establish whether, firstly, software must be regarded as a Medical Device falling under the European Medical Device Directive MDD, and, secondly, whether it also falls under the IVDD (In-vitro Diagnostic Directive 98/79/EC).

In addition, the guideline presents and explains various cases.

**The following stand-alone software products, for example, need not be classified as Medical Devices:**
- Hospital information systems for tasks such as patient admission, scheduling patient appointments, insurance, billing and general patient management
- General information systems used to store, archive and transfer data. However, if the software is used with additional modules, these modules might qualify as Medical Devices in their own right.
- Communication systems for general e-mail, mobile and video communication
- Video software for teleconsulting between clinic and patient

**However, software products may be classified as Medical Devices in the following cases:**
- Decision support software. This includes systems which combine medical knowledge databases and algorithms with patient-specific data and software products that provide recommendations for diagnosis, prognosis, monitoring and treatment of individual patients
- Software which generates alarms based on the observation and analysis of patients’ physiological parameters
- Telesurgery systems, for example, for conducting a surgical procedure from a remote location

The entire MEDDEV 2.1/6 guideline (in English) plus decision diagrams and further examples is available for download [here].

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TÜV SÜD will present itself at the MEDICA trade fair in Duesseldorf, Germany, from October 14 to 17, 2012. Specialists from various areas such as active Medical Devices, non-active Medical Devices, in-vitro diagnostics, international approvals etc. will be available at our Booth B05 in Hall 10. In addition, colleagues from countries including China, Korea and the USA will bring you the latest updates from their countries. Medical Device manufacturers will thus have the opportunity of informing themselves in depth about TÜV SÜD’s global certifications and services. A lecture series is also planned at the trade show.

Focal themes at MEDICA
This year, the TÜV SÜD team will focus on four topical themes:
- Revision of the European Medical Device Directive (MDD)
- European In-vitro Diagnostics Directive (IVDD)
- IEC 62304 – Medical Device software – software life cycle processes
- Amendment 1 IEC 60601-1 3rd Edition

The international experts will answer your questions in personal discussions. We will be happy to make an appointment with you:
www.tuev-sued.de/ps/medica2012
We will provide you with a day ticket to the trade show for the day of your appointment.

MEDICA
MEDICA, the world’s largest medical fair, takes place in Duesseldorf, Germany, every October. There, MedTech manufacturers from all over the world meet and present the whole bandwidth of new products, services and procedures in out-patient and in-patient care.

October 14 to 17, 2012, Duesseldorf
Hall 10, Booth B05
www.medica.de

ARAB HEALTH 2013 in Dubai
TÜV SÜD goes east

The increasing numbers of patients from the Arab world in western health facilities show that the Arab and European health industries have grown very close. In January, the industry’s focus will turn to the east when the 38th ARAB HEALTH opens its doors in Dubai. TÜV SÜD will be represented by a stand in the German pavilion.

ARAB HEALTH, the world’s oldest health exhibition, takes place every year in Dubai. 3,500 exhibitors from 142 countries present their products and services over a total floor space of 47,000 sqm. In 2012, the exhibition plus congress counted 83,278 visitors. Most visitors come from the United Arab Emirates, their neighboring regions and India. Norbert Stuiber, who specializes in the approval of Medical Devices in Saudi Arabia, and colleagues from TÜV SÜD’s branch office in Al-Jubail (Saudi Arabia) will jointly present the entire service portfolio with a focus on active Medical Devices.

January 28 to 31, 2013, Dubai
German Pavilion
www.arabhealthonline.com

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**Standards & EU Guidelines**
- Revision of MDD 93/42/EEC
- IVD Directive 98/79/EC
- IEC 60601-1:2005. 3rd Edition
- Design Dossiers
- Usability of Medical Devices
- Transition to EC Directive 2007/47/EC

**Clinical Affairs**
- Clinical Data Requirements for EC Certificate Extension
- Clinical Data Requirements in Era of 2007/47/EC
- Assessment of Medical Devices Incorporating Material of Animal Origin
- Human Blood Derivatives

**Further Services**
- Quality Management in Dialysis
- EN 60601-2-5 Therapeutic ultrasound devices
- EN 60601-2-37 Diagnostic ultrasound devices
- Medical Device Software

**International Affairs**
- Globalization of Medical Device Approval
- FDA 510(k)
- Access USA and Canada
- Korea
- PAL – MHLW Movement
- Japanese PAL
- PAL – Change application and notification
- PAL – Fundamental Info
- Access Russian Federation (GOST)
- Access Australia
- Chinese Approval for MD

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