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ADVENA NEWSLETTER

FOR NOVEMBER 2016

Your personal update on Medical Device Industry Regulatory and Quality Management News.

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ADVENA REGULATORY NEWSLETTER FOR NOVEMBER 2016

EDITORIAL FOR NOVEMBER

FESTIVE GREETINGS TO ALL OUR CLIENTS

As many of our longer-term clients will understand this November'sreport will be the last for the year, we do not issue another one until the end of January. The net result is that this is quite a long report to finish 2016, sorry but many issues are important.

As for ourselves, the Advena office will close on December 23rd, we will return on January 3rd, but of course, in respect of our legal obligation of the EU Authorised Representative services, emails will always be responded to and the telephone answered if there are emergency or vigilance issues.

Warmest regards from all of us at Advena Ltd and Advena Medical Ltd, we wish you all the best for the festive season and a prosperous New Year.

Lastly we finish our year with the news that we are still expanding and by the time we report again at the end of January we should be able to announce that we have been joined by a senior ex-Notified Body technical File reviewer who as specialties in electronic medical devices and software.

1 ARAB HEALTH SHOW 2017

Advena will have a booth at this important show in Dubai that runs from 30th January to 2nd February 2017.

Details may be found at http://www.arabhealthonline.com/

We will be available to meet clients old and new during this trade show and have access to meeting room facilities at the ABHI UK Pavilion. We advise those who would like to meet one of our team to contact Anthony Kirby (Anthony.kirby@advenamedical.com) well in advance as the meeting room needs to be booked for any extended conversations or product reviews.

2 NEW SERVICE FOR AUSTRALIAN AND NEW ZEALAND REGULATORY APPROVALS

Advena have signed a contract to partner with ACRA Regulatory Services Pty Ltd (Australia) and ACRA Regulatory Services Limited (New Zealand). Their website is: http://www.registermedicaldevice.com.au/

Our contact is Anne Frances Jones and we will expand on this as soon as possible by making changes to our own web-site to provide a clear link.

In the meantime, should you need regulatory assistance in these two new exciting marketing areas, please let us know and we will set the process in motion.

3 US PARTNER

Our partnership with Biomedical Regulatory Consulting, of Houston Texas (www.biomedregulatory.com), is now well established and we have already put several clients in touch with their President, Bill Soller, for help in the USA and Canada. As a reciprocal they are advertising our Advena Ltd. services in the USA.

4 EU MEDICAL DEVICE REGULATORY CHANGES

BSI Consultants Day, Friday 11th November 2016 – Report

On November 11th we attended the annual British Standards Consultants` Day at their European HQ in the UK. The following paragraphs (5 to 15) report on the most important elements (*in italics*) with some elaboration from Advena to clarify issues. (Our additional comments are shown as Notes.)

5 OVERVIEW OF THE STATUS OF NOTIFIED BODIES

There are only 59 EU Notified Bodies (NBs) remaining in the EU who are accredited for certifying medical device manufactures. It is unclear how many will remain once they need re-accrediting to the new EU MDR and IVDR.

The BSI opinion is that any NB will need at least 100 full time assessors / technical people to be able to survive the impending changes. (BSI has currently 217 experts.)

Unannounced audit cycles are now established but the frequency (full cycle) will now be increased from 3 to 5 years. (Although for Class III this will remain at 3 years.) NBs report problems with clients changing addresses without informing the NB so they arrive at the wrong address – but the NB are charging them anyway!

Staffing is always going to be a problem and BSI are advertising world-wide for assessors, and more importantly, clinicians who are needed to assist with technical file reviews. They are also seeking software experts.

NBs will need to accept that many certification audits will now be attended (shadowed) by observers from a competent authority, and this could be any competent authority in the EU. This scrutiny is part of NBs own approval cycle to allow them to retain their own certification to CE audit.

In the future not all NBs will be accredited to CE mark devices with animal implants – all these to be class III.

Advena Note;

We have had our attention drawn to the fact that some Notified Bodies may be having their scopes reduced, i.e. they will no longer be allowed to certify certain types/families of medical devices.

If your Notified Body has had such a change, and it affects your current certification, it is our understanding that they will warn you in good time that you will need to find another Notified Body. At this stage we have only heard this affecting the Czech Notified Body *Institute for Testing and Certification* (NB1023) but there may be others. Would clients please let us know if you receive any further information on this which we can share with all our clients?

6 STATUS OF THE MEDICAL DEVICE REGULATIONS (MDR)

The MDR, all 355 pages compared to the 70 pages of the old MDD, is causing difficulties as the nuances are extensive and some are difficult to follow. The publication was meant to be available in early 2017 but with delays caused by legal reviews, and the need for (legal quality) translation into 24 languages, it could be as late as June 2017 before it is adopted into EU law.

P.S. We have just heard that on 23rd November the translated MDR and IVDR Regulations (in 24 languages) were sent to the Member States for checking – another important stage of their implementation.

The structure of the MDR is such;

- *Chapter I – Scope and Definitions*

- *Chapter II – CE Marking, Economic Operators, Reprocessing*
- *Chapter III – Identification and Traceability of Devices*
- *Chapter IV – Notified Bodies*
- *Chapter V – Classification and Conformity Assessment*
- *Chapter VI – Clinical Evaluation and Investigation*
- *Chapter VII – Vigilance and Market Surveillance*
- *Chapter VIII – Cooperation between Member States*
- *Chapter IX – Confidentiality, Data Protection, Funding, Penalties*
- *Chapter X – Final Provisions*

The 10 processes for manufacturers to assure MDR conformity will be;

1. *Check Device is within Scope of MDR (Chapter I, Articles 1, 2, Annex XV)*
2. *Determine "Device Class" (Chapter V, Article 41, Annex VII)*
3. *Select "Conformity Assessment Procedure" (Chapter V, Article 42)*
4. *Identify Applicable "Safety and Performance Requirements" (Chapter II, Article 4, Annex I)*
5. *Assign UDI (Chapter III, Article 24, Annex V)*
6. *Assemble "Technical Documentation" (Annex II, Annex I, Annex XIII, Annex XIV,…)*
7. *Apply Conformity Assessment Procedure (Annexes VIII, IX, X, or XI)*
8. *Complete "Declaration of Conformity" (Chapter II, Article 17, Annex III)*
9. *Affix "CE Mark" (Chapter II, Article 18, Annex IV)*
10. *Post Market Surveillance and Updates (Chapter VII, Annex IIa, Annex XIII)*

The transition period of 3 years for devices may now be extended to 4 years as there are so many changes. However the IVDR transition should remain at 5 years.

Still waiting for additional "implementation acts" from the EU – to assure there are no discrepancies of interpretation between different EU countries. There are lots of unknowns even for Notified Bodies, including UDI implementation, EUDOMED structure and NBOG codes for NBs scope and designation. (Latter affected by NB competence.) Note the new NBOG codes have been issued for NB knowledge and skills.

There is still a question as to how and when the new essential "common technical specifications" will appear.

It is agreed that tattooing and piercing devices are not "Medical Devices" although dermal fillers and liposuction equipment are. Manufacturers have to make decisions as to what is defined as a "medical device" and such a rationale will need to include a detailed risk-benefit input. Note; aging is not a "medical purpose!"

7 REPROCESSING SINGLE-USE DEVICES- MDR ARTICLE 15

The new regulations clarify the control needed for reprocessing single use devices as now often undertaken for very expensive items of equipment that are packaged and presented in hospitals as "single use".

With the new regulations the company / hospital undertaking the reprocessing will need to document at least, but not limited to.

- *Exchange of information with the original manufacturer.*
- *Incoming / start-of-process inspection.*
- *Essential requirement check list.*
- *Risk management study.*
- *Post market clinical follow up trail.*
- *Validations for cleaning.*

- *Validate reuse durability, performance and mechanical qualification. Include documented check for material condition, sharpness, hinges, shape distortion as applicable.*
- *Track number of times reprocessing is done for each device.*
- *How the reprocessed device will be identified and tracked back to the original.*
- *Traceability to the original LOT / SN traceability – particularly if the device moves from original location.*
- *Assure vigilance regulations are followed, particularly for tracking of common/recurring problems.*
- *Check that there are no biocompatible changes after re-sterilisation. (Steam, EO, RAD as used.)*
- *Document the way repackaging and labelling will be done. (LOT or SN, dates, expiry?)*

8 NEW MDR CLASSIFICATIONS

There are specific and substantial changes to classification rules 2, 3, 4, 5, 6, 8, 9, 10(a) and 13.

In particular:

- *Reusable surgical instruments will now be subject to NB review, NBs not sure if this will involve a site audit for each manufacturer. Advena will be working with BSI for some simple technical file template options. (Release in New Year.)*
- *New rules 17, 19 for nano-particles, and 21 for ingestible devices.*
- *Rule 22 covers inhalers – now Class II(a).*
- *Many cosmetic devices are now in Class II(a)*
- *There are custom made classification changes*

However general low-risk software is still Class 1.

9 NEW IVD REGULATIONS (IVDR)

The definition of an IVD is:

a) …any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system,

b) whether used alone or in combination, intended…to be used in vitro for the examination of specimens, including blood and tissue donations… from the human body,

c) solely or principally for…providing information..

But what is NOT an IVD is:

(a) Products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

(b) Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;

(c) Internationally certified reference materials;

(d) Materials used for external quality assessment schemes.

Only about 10% of IVDs will stay in the existing self-certification group A as many low class IVDs are now moved into higher classes. All classes B to D will need NB intervention / certification.

Clinical performance / benefit / outcomes / intended population will be important to document although many IVDs still do not have common technical specifications available. Grandfathering will not always be possible and some clinical evidence will always be needed.

Clinical benefit will be important to document. Clinical benefit of an IVD relates to accurate medical information and final clinical outcome. Also clinical performance that links to the scientific validity and analytical performance.

Manufacturers need a plan, risk studies, formal clinical evidence and perhaps new trials for even old IVD devices.

Post Market Clinical Follow-up, as a live part of the manufacturer's 13485 Quality System is essential. IVD manufacturers will need procedures and a PMCF plan.

If an AR is needed for non-EU IVD manufacturers the AR must have 4 years' experience.

10 CLINICAL DATA – THE BIG ISSUE

The big question now is how equivalence may be used, or not used, in clinical safety and efficacy studies. Manufacturers will no longer be allowed to use data from other manufacturers of competitive devices unless permission is granted to use the information. If permission is received the recipient must then ensure (document) that the data is up-to-date and represent the latest post-market data on the device referred to.

Published data can be used (peer review essential) but should be up-to-date so as to demonstrate "state of the art". And then the whole article to be used and analysed, not just an abstract.

Data use must always be relevant to the device and intended use and refer to anatomical locations, ethnic groups, high risk populations, population usage to show the data is correct for the manufacturer's intended market.

If no data is available then the manufacturer must undertake clinical trials, or use lots of data on their own product. Clinical trials are always needed for start-up devices, for all classes.

NBs are admitting they are short of expertise but are recruiting all over the world.

Once a device is launched clinical performance must be tracked by PMCF for at least 5 years and ongoing records should be retained for all devices. Implants should be tracked for the whole device lifetime. Manufacturers must consider (encourage) news of any unreported events from doctors / surgeons via the sales team.

Evidence should be cross referenced to an essential requirement check list and a full 14971 risk study is always needed to compliment safety and efficacy.

FDA data can be used from their web-site, particularly related to vigilance.

In the future some EU vigilance info on competitive devices may be available from the new EUDOMED data base.

For assuming equivalence:

- *Each device with which equivalence is claimed must fulfil all clinical, technical, biological characteristics.*
- *Differences between the device under evaluation and the device presumed to be equivalent need to be identified, fully disclosed, and evaluated; explanations should be given why the differences are not expected to significantly affect the clinical safety and performance.*
- *Potential impact of differences in manufacturing processes on technical and biological characteristics should be considered.*
- *Where possible, clinically relevant specifications and properties should be measured both in the device under evaluation and the device presumed to be equivalent, and presented in comparative tabulations*
- *Comparative drawings or pictures should be included in order to compare shapes and sizes of elements that are in contact with the body.*

- *Material characterisation and comparative testing in accordance with ISO 10993 series should be undertaken to demonstrate biological equivalence.*
- *Data required to demonstrate equivalence should be summarised in the clinical evaluation, and the location of supporting information in the technical file cited.*

**Similar means that no clinically significant difference in the performance and safety of the device would be due to differences.*

Only clinical data obtained, when the equivalent device is a CE-marked medical device used in accordance with its intended purpose as documented in the IFU, will be considered relevant.

Note: Exceptions can be considered when the equivalent device is not a CE-marked device. Then information concerning the regulatory status of the equivalent device and a justification for the use of its data should be included in the clinical evaluation report. The justification should explain if the clinical data is transferrable to the European population, and an analysis of any gaps to good clinical practices (such as ISO 14155) and relevant harmonised standards.

When submitted all clinical evidence for class II (b) and III will be subjected to independent EU scrutiny.

Clinical evidence documents need at least a 2 – 5 year review depending on the classifications. For new devices or implants the data should be reviewed every year. Also all devices need a PSUR report (Periodic Safety Update Report) and such reports should be signed off by qualified product specialist.

Manufacturers must have a clinical evidence SOP to describe the process used, the planning process, the need for establishing state of the art design requirements, and ongoing use PMCF.

For all technical files BSI inspectors will expect references to MEDDEV 2.7.1 rev 4, and at least a cross check (gap analysis) to old rev 3 data if that had been already done. Data will be examined by experts for quality of data, bias, errors, inadequate disclosure, and misinterpretation.

Comparisons will be allowed to same device 510(k) submissions to save duplication.

Conclusion must show equivalence to data in respect of intended use, indications and contra indications, design, technical attributes, design, processes, biological safety (reaction to the body, degradation, and leachability), clinical performance etc. IFU must relate to all and be understandable for prospective users. IFU warnings and precautions should relate.

Documents for high risk device will / may be double checked by MHRA so NBs take no chances. NB charges will be very high due to amount of work involved.

11 UNIQUE DEVICE IDENTIFICATION (UDI)

Still not clear which bar code standard will be used on devices although the GSI (supermarket type code) has preference. Implant cards (traceability) will be issued to patients.

12 ISO 13485: 2016

The end of transition period for the use of this updated standard will be early 2019 and then all manufacturers requiring a certified QMS must comply. However, BSI stated that the new standard could have minor changes once the MDR is issued

There will be a CEN technical report shortly to compare clauses of 13485 new and old.

Advena note;

We have had this information about this Quality Management update in Australia. This article is from the Therapeutic Goods Administration (TGA) and was dated August 9, 2016: Medical Device Quality Management Systems: Transition To New Standard

And for the transition in Canada go to; http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/iso13485-trans-notice-avis-eng.php

13 MDSAP AUDITING

The Medical Device Single Audit Programme, MDSAP, covers conformity to ISO 13485 plus some specific country requirements. It was developed to allow a single audit / certification that is accepted by USA, Canada, Brazil, Japan and Australia.

MDSAP audits are on a 3 year cycle + unannounced visit and each audit covers a full cycle of all sections of 13485, however there is no design sampling.

At the moment it is not accepted by the EU although EU bodies (e.g. BSI) have been involved in the preparation.

Canada will insist on MDSAP certification by the end of 2018. It is noted that this could be a very expensive process and may not be cost effective for small companies with limited sales in Canada.

Audits will take up to 6 ½ days and based on fixed prices per segment and hence could cost circa US $5,000 plus!

So far 150 companies have signed up.

14 VIGILANCE

In future vigilance reports must always be reported formally to the appropriate NB (scheme manager) as well as to competent authorities. In future they will then also go onto EUDOMED.

Note the timing of sending in reports which will be, depending on severity;

- *Immediately without unjustifiable delay*
- *2 days*
- *10 days*
- *Or 15 days.*

Details in MDR Chapter VII – Vigilance and Market Surveillance.

Advena note;

There is concern also about under-reporting from EU hospitals as doctors try to keep a low profile when there have been adverse events.

This has also been noted in the USA. *QMed Daily* recently circulated an article on the same subject; this is an abstract;

…..FDA is inching closer to enforcing medtech adverse event reporting requirements, following inspections of 17 hospitals that failed to report events linked to power morcellators and contaminated duodenoscopes.

The December 2015 inspections revealed that those hospitals, and probably many more, failed to train staff or even have procedures in place for reporting such events, writes Jeffrey Shuren, M.D., FDA's director of the Center for

Devices and Radiological Health (CDRH), in a blog post this week. Medtechsafety issues often go unidentified until multiple patients get hurt or die, such as during the superbug outbreaks linked to dirty Olympus duodenoscopes….

15 DOCUMENTATION

Manufacturers must assure that for all technical file documents they have a procedure for a process to assure periodic reviews / updates.

PMCF – proactive data collection, must be planned and documented for each device placed on the market. Reports should refer to plan, experiences, conclusions and any proposed corrective measures.

16 NEW REGULATIONS – AVAILABILITY OF TECHNICAL DOCUMENTATION

Following on from the above comments at the BSI Consultants Day it is important to re-emphasise the changes next year and how we, if we are your Authorised Representative, will need to act in respect of verifying client technical documentation.

In particular:

All medical devices must have a technical file. This has always been the case but with the new regulations this will be policed as importers and authorised representatives will have to legally verify that the documents exist and that they would be available to the authorities if asked for. This will include Class 1 devices, and simple IVDs which traditionally had no official scrutiny that a technical file exists.

In the New Year, and at least before April 1st (a deadline we believe will be most appropriate for the new EU regulations) we will be asking all non-EU AR clients for some specific information before we are legally able to renew any AR contracts.

This will include, but not be limited to a Declaration of Conformity in a new format (we will supply a template) where the manufacturer signs to say they have a technical file as required by the MDR (or IVDR as appropriate) and that such data would be available to EU authorities upon request. The Authorised Representative (us) also needs to sign/declare this declaration to demonstrate that they have verified the existence of such technical documents. It is possible that the importer will also have to be involved.

This Declaration would need to explicitly list all the devices that are CE marked and covered by the Declaration by identification description and number.

Note: - At this stage we envisage needing to see / verify at least the following technical file data covering each CE marked device.

- Product description, intended use and device classification.
- Essential requirement check list. (We already have templates available for this in respect of the new regulations.)
- Risk management study that follows at least the format of EN IO 14971.
- A document that demonstrates safety and efficacy, ideally following the format of MEDDEV 2.7.1 revision 4.

In the cases of medical devices that have been CE certified by a Notified Body we will be obliged to verify the existence of the Notified Body EC certificate which clearly defines the same medical devices as listed on the Declaration of Conformity.

In addition, as per the paragraph 24 below on product liability, we will be needing a certificate of product lability insurance.

These requirements will be ratified once we know exactly and final wording of the new regulation; probably by February next year. You have been warned.

17 MHRA TO INCREASE FEES

The MHRA have announced their proposal to increase fees next year.

See
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/572166/Consultation_document.pdf

At the moment the only item that may affect some clients (unless you are registering clinical trials in the UK) is the registration fee increase by 42%. Could now make the UK more expensive than registering in Malta, your alternative with us.

18 EMC TESTING – A NEW STANDARD

Notified Bodies have warned us that Standard IEC 60601-1-2, 4th Edition increases the compliance focus on the EMC profile of the equipment and they will be looking much closer at this are in future. We have had this addressed by a Notified Body specialist and they say;

The most significant changes with respect to the previous edition include the following modifications:

1) *specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;*
2) *specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT that was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;*
3) *specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;*
4) *specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and – better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term "life-supporting";*

Plus the following additions

1) *guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;*
2) *guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;*
3) *guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and*
4) *guidance on identification of IMMUNITY pass/fail criteria.*

Besides the above changes and additions, the biggest is probably the introduction of ISO 14971 within the 4th Edition. Now all manufacturers testing their devices under the 4th Edition must provide the Risk Management File to the testing house, and the RMF must be in accordance with ISO 14971 (the standard is specified within the 4th edition).

A lot of manufacturers are struggling with the concept of the RMF but in my view this is not a change at all, the MDD already states that risks must be reduced ALAP although it is true it does not require specifically ISO 14971, and the EMC 4th edition RMF assessment is performed strictly from an EMC risks point of view

In summary:

Significant Changes Include:

1) *New categories of Environment*
2) *New Safety and Performance Requirements*
3) *Requires Test Plan Preparation Form from Manufacturers*
4) *Increased Immunity Test Levels*
5) *Lower Limits no longer allowed*
6) *Safety Engineering into Medical EMC/Risk Management*

The new version will introduce new product categories, more stringent test levels and some new concepts, such as immunity test for RF proximity, wireless communication equipment and EMC risk assessment. Due to such changes unfortunately almost all devices within its scope will need to be re-tested partially or in full depending on the product's category and safety and performance criteria, therefore a gap analysis only will not be sufficient (it is good if the manufacturer perform the gap anyway).

Finally, I'd like to add the fact that the current MDD requires that manufacturers takes the state of the art as the principle for their devices, and state of the art means also using the latest harmonized standards.

We have been made aware that Intertek are running a course on EMC next year, this was their invite, it could interest some UK clients;

We are running a special training course on EMC for Medical Equipment & Systems. The course covers procedural and technical differences between the three versions of IEC60601-1-2 currently in use today.

The course is on February 7th 2017 if you would like to book please see http://www.intertek.com/training/uk/

19 CHINA

We are now working on an agreement with a consultancy company operating out of China who could assist with Chinese regulatory approvals, and they have provided this interesting summary.

Medical devices that are imported in China have to be registered at China Food & Drug Administration (CFDA) in Beijing

CFDA has been founded in 1998 as equivalent to the U.S. FDA. CFDA is responsible for medical devices, drugs, healthcare services, cosmetics, food. Their headquarters is located in Beijing, with offices in each province. There is a pre-market approval department of Medical Device Registration and a post-market supervision department of Medical Device Supervision.

The compilation of the technical requirements is the first step for registration of imported Class II and III medical devices in China. The sample testing is done based on these requirements. If the testing result is deemed unsatisfactory, the Center for Medical Device Evaluation (CMDE) may request the company to revise the technical requirements and conduct a re-test. The technical requirements should describe the product and include the appropriate Chinese standards it complies with. Therefore, the manufacturer should provide sufficient information to support the drafting of Chinese technical requirements by the registration agent. Many of the Chinese standards correspond to international standards. But there can be problems in the initial registration if the product standard is too vague or if the applied international standards are different to the Chinese standards. Any product information (like product numbers, dimensions, etc.) noted in the technical requirements should exactly match other legal documents.

The testing centers will use the technical requirements to determine what tests to conduct and how many test samples are required for type testing. Often the CFDA might request more samples than the actual need or ask for propriety information. CFDA has not accredited any foreign lab therefore only Chinese labs approved by CFDA can be ordered for type testing. While the type testing is in progress, it is possible to update the technical requirements. Once the Type Testing has been completed, the technical requirements cannot be revised. Therefore it is very important that the information are correct and supported by legal documents. The test report is only valid for one year. The sample testing usually takes 6 months.

The CFDA has been organizing expert review meetings to determine if clinical trials in China are required for product registration. There is a list of 8 medical devices that require clinical trials conducted in China. If the product is listed on the exemption lists, there are no clinical trials in China necessary. For the other products it is possible to provide clinical data complying with CFDA standards. If these data are sufficient in order to compile a qualified clinical evaluation report, clinical trials can also be avoided. In all other cases clinical trials in China are mandatory.

The initial application for Class II and III medical devices registration comprises of a total 15-20 documents, depending on the functions of the medical device. They must be collected and submitted to the CFDA in one batch including testing report issued by CFDA certified testing center. The preliminary review and issuing of the acceptance notice takes 5 working days.

The technical review of the registration dossier takes 60 working days for Class II products and 90 working days for Class III products. CFDA will likely submit a supplementary notice after the technical review and request further information. Additional testing might also be required according to the supplementary notice. Supplementary documents must be submitted to the CFDA within one year to start the second technical review. The second technical review will take up to 60 working days. If the issues cannot be resolved or the documents are not sufficient, the application will be rejected. CFDA will determine whether the approval will be granted within 20 working days and the certificate issuance by CFDA takes 10 working days. The certificate is valid for 5 years.

Imported Class I medical devices need to be filed at the CFDA counter in Beijing. There are 8-13 documents including a testing report required for a new filing. After submission of these documents they are reviewed and in case they are accepted the filing will be done immediately. Class I filing has no expiry date. All CFDA certificates and their validity are entered into a CFDA database.

If any clients are interested in pursuing the opportunity of selling in the huge Chinese market please let us know.

20 US FDA AND Mr. TRUMP!

Early days yet, but several commentators have suggested that Trump may want a clean house at the top of federal agencies, including the FDA and it would appear has a desire to cut bureaucracy, I am sure this would be welcomed by manufacturers.

On November 23rd Fox News said

"Between a Trump presidency and a radically pro-business Congress, the next few years may see a removal of numerous consumer protections," said Michael Jacobson, co-founder and president of the Center for Science in the Public Interest.

For Trump and his advisers, including Newt Gingrich, the agency has for too long acted as a barrier to medical innovation.

This would be an interesting move while the EU is tightening regulations FDA could make it easier!

I am sure our US clients will have thoughts on this.

21 WHERE CAN AN AUTHORISED REPRESENTATIVE BE BASED?

Forgetting all the unresolved Brexit questions there have been some questions about the legality of authorised representatives based in Iceland, Switzerland, Turkey etc. who are outside the EU but have some form of agreement with the EU.

The question as raised by the EAAR trade association;

EAAR (European Association of Authorised Representatives) is seeking clarification regarding the legal acceptability of designating authorised representatives under Directive 93/42/EEC in countries outside the European Union which have agreements with the EU. I am referring specifically to the EEA countries (Iceland, Liechtenstein and Norway), Switzerland (MRA) and Turkey (under the customs union provisions).

We have recently become aware of a new opinion that designation of authorised representatives in the sense of Directive 93/42/EEC is not allowed in these countries. We have assumed in the past that such designation is possible.

We have yet to get a clear answer on this – it appears to have been spurned by the legal situation described in the new MDR and IVDR. However what is clear is that both the UK (at present) and Malta are and will be approved havens for EU Authorised Representatives. We have heard, however, that Turkey will be removed as there is no indication that this country will be accepted for EU membership --- yet!

22 PRODUCT LIABILITY INSURANCE

As reported earlier in this month's Newsletter, translated Regulations have been sent to the Member States. (We have seen the Dutch version only but we are assuming it has gone to all member states as that was the intention.) At this stage they are distributed to allow comment on errors in the translation, not on the actual content.

The important point here is that article 11.5 on product liability responsibilities has not been removed or changed.

This will mean, as discussed many times in our Newsletters, that the requirements for manufacturers who CE mark devices must have adequate and appropriate product liability insurance. This has not gone away.

We will be dealing with this issue with our Authorized Reprehensive clients in the New Year but the proposal now will probably be that we will be unable to legally take on new AR clients, or renew AR mandates, unless the manufacturer provides us with an authentic product liability insurance certificate that cover all EU countries and absolves the authorized representatives from product liability responsibilities. (The latter is important for legal issues as the AR can have no responsibility or control over design, manufacture, or safety of client's medical devices.)

25 RECENT FIELD SAFETY CORRECTIVE ACTION REPORTS

3M Health Care 31 October 2016 Surgical, diathermy Model: 3M™ Universal Electrosurgical Pad, solid, uncorded MHRA reference: 2016/011/003/701/008
Abbott: ARCHITECT Toxo IgM 14 November 2014 IVDs, viral microbiology MHRA reference: 2016/011/015/701/016
B. Braun Melsungen: UREOFIX 500 CLASSIC 24 October 2016 Urine collection devices and accessories Model: 4417930, 4417920, 4417910 MHRA reference: 2016/010/026/291/009
B. Braun: Dialog+ Dialysis machines with SW 8.2A with option Adimea fitted 14 October 2016 Dialysis, haemodialysis Model: Dialog+ - complete list to follow MHRA reference: 2016/010/014/601/010
Bausch + Lomb: EasySept Hydro Plus Peroxide Solution 28 October 2016 Contact lenses, care products Model: EasySept Hydro Plus MHRA reference: 2016/010/028/291/015
Bayer: Medrad® IntegoPET Source Administration Sets November 2016 Infusion & transfusion, administration sets MHRA reference: 2016/011/010/291/009
Bellco: Formula, Formula Plus, Formula 2000, Formula 2000 Plus, Formula Therapy, Formula Domus October 2016 Dialysis, haemodialysis MHRA reference: 2016/010/021/291/017
Biomet UK: Rebalance Ankle Talar Culcus Guides 28 October 2016 Orthopaedic surgical instruments - measuring tools MHRA reference: 2016/010/028/701/013
Brainlab: BrainLAB Knee 23 September 2016 Surgical navigation system MHRA reference: 2016/010/024/701/009
Cepheid: Xpert ®MRSA Blood culture assay 7 October 2016 IVDs, bacteriology MHRA reference: 2016/010/028/299/010
CME Medical: CME Ambulatory Syringe pumps - T34, T60 and TPCA FSN2016-004 Infusion systems Model: T34 - 100-lOOSM, T60 -100-100PSLM, TPCA - 100-106PSLM, PMP000 MHRA reference: 2016/010/027/291/017
Compression Works: AAJT Abdominal Aortic Junctional Tourniquet 7 November 2016 Surgical equipment, tourniquets Model: 63000 MHRA reference: 2016/011/007/601/005
Concert Medical: Galeo Pro Coronary Guide Wire 9 November 2016 Vascular cannula/catheter accessories Model: Galeo Pro Coronary Guide Wire; 389781, 389782, 389783, 389784, 389785, 389786, 389787, 389788, 389791. MHRA reference: 2016/011/008/601/020
Corin: Trinity 31 October 2016 Joint prosthesis, hip Model: 104.2800, 104.3200, 1043600, 104.4000, 104.2805, 104.3205, 104.3605, 104.4005, 104.2810, 104.3210, 104.3610, 104.4010, 104.3215, 104.3615, 104.4015, 321.01.425, 321.02.432, 321.03.436, 321.04.436, 321.05.436, 321.04.440, 321.05.440 MHRA reference: 2016/010/031/601/010
Depuy Synthes 11 November 2016 Surgical instruments, non-articulated cutting Model: 352.044; 352.040 MHRA reference: 2016/011/016/299/014
Draeger: Infinity Acute Care System (M540) October 2016 Monitors, patient Model: MS25510, MS25520, MS26372 MHRA reference: 2016/011/008/291/003

EKF-diagnostic: Quo-Test HbA1c Analyzer 26 May 2016 Quo-Test HbA1c Analyzer Model: 0108 MHRA reference: 2016/010/011/701/012
Elekta FCA-EIAB-0004 Radiotherapy Model: 715000 (Perfexion) 1016200 (Icon) MHRA reference: 2016/004/005/701/011
Exactech: Equinoxe Reverse Shoulder Defining Screw Kit 17 October 2016 Joint prosthesis, shoulder Model: Equinoxe Reverse Shoulder Fixed Angle Torque Defining Screw Kit MHRA reference: 2016/011/004/701/024
Gambro: 115244: AK 98, 230V, Efficient 115248: AK 98,230V, Bio Version, 115250: AK 98, 230V, Self-Care 955403: AK 98, 230V Bio, v2 November 2016 Dialysis, haemodialysis Model: 115244, 115248, 115250, 955403 MHRA reference: 2016/011/001/291/015
GE Medical: Innova x100 FMI 12254 X-ray, fluoroscopy systems Model: Innova x100 MHRA reference: 2016/010/027/701/008
Gyrus ACMI: Port Seal and Y-Connector 1 November 2016 Endoscopes, flexible Model: AUR-BP, UBP-Y MHRA reference: 2016/011/004/601/011
Handicare: Vertical Support 1 November 2016 Hoists and slings Model: 50400242, 50400190, 50400235 MHRA reference: 2016/011/007/291/004
IMPAC Medical Systems: Monaco RTP System October 2016 Radiotherapy planning and verification systems MHRA reference: 2016/011/001/701/002
IMPAC Medical: Monaco RTP System October 2016 Radiotherapy planning and verification systems MHRA reference: 2016/011/014/701/006
Inpeco: Aptio and FlexLab by Inpeco 25 October 2016 IVDs, clinical chemistry MHRA reference: 2016/010/026/601/010
Intuitive Surgical: da Vinci® Xi™ Surgical System 20 October 2016 Endoscopes, rigid Model: IS4000 Surgical System 380677 / SS4000 380652 / PS4000 MHRA reference: 2016/010/021/701/014
Leonhard Lang: Defibrillation electrode SCHILLER DF87C and DF56C 27 October 2016 Defibrillators, non-implantable Model: DF87C, DF56C MHRA reference: 2016/010/028/299/006
Mako Surgical: Offset Cup Reamer Handle 17 October 2016 Surgical power tools Model: Offset Cup Reamer Handle MHRA reference: 2016/011/004/291/006
Mathys: balanSys UNI convex PE inlays x/5 8 November 2016 Joint prosthesis, knee Model: 77.30.0211; 77.30.0221; 77.30.0231; 77.30.0241; 77.30.0251 MHRA reference: 2016/011/009/071/001
Maxilabs: Sodium Bicarbonate ear drops 10ml 9 November 2016 Substances for topical application (non-pharmaceutical) Model: Ear wax softener MHRA reference: 2016/011/008/291/001
MED-EL: SONNET Mini Battery Pack Cable 27 October 2016 Implants, active, hearing MHRA reference: 2016/010/028/701/014
Medline International: Sterile Procedure Trays 26 October 2016 Surgical devices, non-powered MHRA reference: 2016/011/004/701/018
Medtronic: Affinity Fusion™ Oxygenator with Integrated Arterial Filter and CVR November 2016 Infusion and transfusion, heart lung circuits Model: BB841 MHRA reference: 2016/011/016/299/023
Medtronic: Charging System, RestoreSensor Charging System FA735 Implants, active, stimulators, neuro Model: Model 37751 Recharger included in Model 37651 Charging System for Deep Brain Stimulation (DBS), Activa RC (Model 37612) MHRA reference: 2016/010/026/291/001
Medtronic: SynchroMed® II Implantable Drug Pumps October 2016 Implants, active, infusion pumps Model: 8637-20, 8637-40 MHRA reference: 2016/010/021/291/014
Molnlycke Healthcare: ProcedurePak trays containing Light Handle Cover (Devon™ Light Glove) 24 October 2016

Surgical devices, non-powered MHRA reference: 2016/010/026/291/007
Nipro Corporation: SFS-5-25P 24 October 2016 Infusion & transfusion, connectors MHRA reference: 2016/010/024/291/036
Orion: QuikRead go instrument sw version 7.1.10/iFOBT 25 October 2016 IVDs, clinical chemistry MHRA reference: 2016/010/026/701/002
Philips: Brilliance iCT SP, Brilliance iCT, Brilliance 64, Brilliance 40, Brilliance16, Brilliance 16P, Brilliance 10, Brilliance 6, Brilliance Big Bore Oncology, Brilliance Big Bore Radiology, Ingenuity Core, Ingenuity Core128, Ingenuity CT 26 October 2016 Computed tomography Model: please see FSN MHRA reference: 2016/011/001/299/001
Radiometer Medical: PICO70 FAN 915-352 Storage and collection devices MHRA reference: 2016/011/009/701/014
Research Instruments: EZ-Tip 3 October 2016 Laboratory equipment associated with IVF, cells, tissues MHRA reference: 2016/010/003/701/006
Schaerer Medical: schaerer® axis 21 September 2016 Operating table Model: axis 400/500/600/700/800 MHRA reference: 2016/010/021/701/001
Siemens Healthcare: ADVIA 560 Hematology System 24 October 2016 IVDs, haematology Model: SMN 11170842 MHRA reference: 2016/010/024/601/006
Siemens Healthcare: Chemistry Calibrator 11 October 2016 IVDs, clinical chemistry MHRA reference: 2016/010/011/601/006
Siemens Healthcare: Combi Dockable Table Neurosurgery 10 October 2016 Magnetic resonance, equipment & accessories Model: 10684336 / 10684337 MHRA reference: 2016/010/011/601/005
Siemens Healthcare:ADVIA Centaur Vitamin D Total 11 October 2016 IVDs, clinical chemistry Model: 100 Test kit SMN 10699201; 500 Test kit SMN 10699533 MHRA reference: 2016/010/011/601/003
Siemens: AXIOM Artis systems with SW version VB35E 27 October 2016 X-ray, fluoroscopy systems MHRA reference: 2016/011/016/601/007
Siemens: Business Area Advanced Therapies: Artis Q systems with SW version VD11 27 October 2016 X Ray, Fluoroscopy dystems Model: all Artis Q systems with SW version VD11 and Gigalix X-ray tubes MHRA reference: 2016/011/016/601/005
Siemens: Business Area Advanced Therapies: Artis zee systems with SW version VC21C, VD11 27 October 2016 X Ray, Fluoroscopy systems Model: Artis zee systems with SW version VC21C, VD11 and MegalixCat + X-ray tubes MHRA reference: 2016/011/016/601/008
Siemens: IMMULITE 2000/IMMULITE 2000XPi PSA 4 November 2016 IVDs, clinical chemistry Model: please see additional information MHRA reference: 2016/011/003/601/014
Siemens: SOMATOM Definition AS and SOMATOM Definition Flash 4 October 2016 Computed tomography Model: 08098027 (SOMATOM Definition AS), 10430603 (Flash) MHRA reference: 2016/011/016/601/010
Signus: ROTAIO, cervical disc replacement prosthesis 07 September 2016 Spinal implants MHRA reference: 2016/010/024/291/003
Solmedia: FORM020 NCN-100369 IVDs, cytopathology & histopathology MHRA reference: 2016/010/031/701/003
Spacelabs: Xhibit Central Station 18 October 2016 Monitors, patient Model: 96102 MHRA reference: 2016/010/025/291/011
Spiggle & Theis Medizintechnik: Inflation device 19 Feburary 2016 Vascular cannula and catheters Model: 2080-9030020 MHRA reference: 2016/009/007/701/011
St. Jude Medical: Nanostim Leadless Cardiac Pacemaker (LCP) system 28 October 2016 Implants, active, pacemakers MHRA reference: 2016/010/027/291/016

Stryker: 2.3MM Tapered Router RA2016-060 Surgical power tools MHRA reference: 2016/007/011/291/020
Stryker: Cup Positioner / Impactor Handle Assembly RA 2016-107 – UPDATES Orthopaedic surgical instruments - impacting tools Model: Cup Positioner / Impactor Handle Assembly 2101-0200 MHRA reference: 2016/008/025/291/021
Teleflex Medical: Mucosal Atomization Device (MAD) 28 October 2016 Drug delivery system MHRA reference: 2016/010/028/291/014
Teleflex Medical: Mucosal Atomization Device (MAD) FlexiNozzle Laryngo-Tracheal MAD, MADgic Endotracheal MAD, MADett 28 October 2016 EIF-000100 Nebulizers Model: As per FSN MHRA reference: 2016/010/031/299/012
Teleflex: 7 November 2016 Surgical instruments, minimal access Model: ARROW® OnControl® Bone Lesion Biopsy System Tray, ARROW® OnControl® Aspiration System Tray, ARROW® OnControl® Bone Lesion Biopsy System Tray, ARROW® OnControl® Bone Lesion Biopsy System Trays ARROW® OnControl® Bone Marrow Biopsy System Comprehensive Tray, ARROW® OnControl® Bone Marrow Biopsy System Tray, ARROW® OnControl® Ported Aspiration System Tray, ARROW® OnControl® System Sterile Procedure Tray, OnControl® Biopsy System Ported Needle Tray MHRA reference: 2016/011/008/299/007
Trinity Biotech: Bio-Rad RPR 100/Bio-Rad RPR 500/Bio-Rad RPR Cards 21 October 2016 IVDs, bacteriology MHRA reference: 2016/010/027/701/010
Trinity Biotech: MicroTrak® RPR Syphilis 21 October 2016 - R019-16 - MicroTrak® RPR Syphilis IVDs, bacteriology MHRA reference: 2016/010/024/291/026
Trinity Biotech: MicroTrak® Syphilis TPHA 21 October 2016 IVDs, bacteriology MHRA reference: 2016/010/024/291/025
Ulrich: Surgical Technique uCentum - Locking Screw I-00227 Osteosynthesis, bone screws Model: CS 3801-01 – Locking Screw MHRA reference: 2016/011/016/299/011
Ulthera: Cellfina System 14 November 2016 Surgical devices, non-powered MHRA reference: 2016/011/015/701/007
Various: heater/cooler units 11 November 2016 Blood/fluid warming systems MHRA reference: 2014/007/016/081/003
Wright Various 8 November 2016 Sterilization, healthcare MHRA reference: 2016/011/011/291/016
Zimmer: Java Posterior stabilization System 19 October 2016 Orthopaedic surgical instruments - Insertion/extraction tools Model: SN2023-1-00401 MHRA reference: 2016/010/020/291/013

27 UPDATED STANDARDS

BS EN PUBLICATIONS	
BS EN ISO 5361:2016	Anaesthetic and respiratory equipment. Tracheal tubes and connectors
BS EN ISO 5364:2016	Anaesthetic and respiratory equipment. Oropharyngeal airways
BS IMPLEMENTATIONS	
BS ISO 3999:2004	Radiation protection. Apparatus for industrial gamma radiography. Specifications for performance, design and tests
BS ISO 7206-12:2016	Implants for surgery. Partial and total hip joint prostheses. Deformation test method for acetabular shells
BS ISO 14242-2:2016	Implants for surgery. Wear of total hip-joint prostheses. Methods of measurement
BS ISO 14243-2:2016	Implants for surgery. Wear of total knee-joint prostheses. Methods of measurement

NEW WORK STARTED	
EN 13704	Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)
EN ISO 20127	Dentistry. Powered toothbrushes. General requirements and test methods
ISO 8600-3	Endoscopes. Medical endoscopes and endotherapy devices. Determination of field of view and direction of view of endoscopes with optics
ISO 8600-5	Endoscopes. Medical endoscopes and endotherapy devices. Determination of optical resolution of rigid endoscopes with optics
ISO 14879-1	Implants for surgery. Total knee-joint prostheses. Determination of endurance properties of knee tibial trays
ISO 20387	Biotechnology. Biobanking. General requirements for biobanking
ISO 21850	Dentistry. Materials for dental instruments
ISO 21881	Sterile packaging of ready for filling cartridges
ISO 21882	Sterile packaging of ready for filling vials CH/212
ISO 81001-1	Health software and health IT systems safety, effectiveness and security. Foundational principles, concepts, and terms
IEC PUBLICATIONS	
IEC 61754-32:2016	Fibre optic interconnecting devices and passive components. Fibre optic connector interfaces. Type DiaLink connector family
IEC 61754-34:2016	Fibre optic interconnecting devices and passive components. Fibre optic connector interfaces. Type URM connector family
ISO PUBLICATIONS	
ISO 7206-2:—	Implants for surgery. Partial and total hip joint prostheses. Articulating surfaces made of metallic, ceramic and plastics materials
ISO 8536-13:2016	Infusion equipment for medical use. Graduated flow regulators for single use with fluid contact
ISO 10938:2016 (Edition 2)	Ophthalmic optics. Chart displays for visual acuity measurement. Printed, projected and electronic
ISO/IEEE 11073-10418:—	Health informatics. Personal health device communication. Device specialization. International Normalized Ratio (INR) monitor
ISO 14644-14:2016	Cleanrooms and associated controlled environments. Assessment of suitability for use of equipment by airborne particle concentration
ISO 16645:2016	Radiological protection. Medical electron accelerators. Requirements and recommendations for shielding design and evaluation
ISO 17509:2016	Dentistry. Torque transmitter for handpieces

28 YOUR PRIMARY CONTACTS AT ADVENA

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