The European Parliament building in Strasbourg, France

The proposed EU regulations for medical and in vitro diagnostic devices

An overview of the likely outcomes and the consequences for the market

Gert Bos, Head of Regulatory and Clinical Affairs at BSI
Erik Vollebregt, Partner at Axon Lawyers

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Introduction

The proposals for the new Medical Devices Regulations (MDR) and In Vitro Diagnostic Devices Regulations (IVDR) will provide a new regulatory framework for medical devices in the EU for the coming decades. The proposals were revised following a political move for more centralized and pre-market controls on higher risk medical devices.

The proposals for the new MDR and IVDR started out as a modest mid-life update to the existing directives. However, they were significantly amended following an additional impact assessment related to several highly publicized issues with medical devices in the EU market that sparked a political wish for more centralized and pre-market controls on higher risk medical devices.

This white paper discusses the most important items in this revision as per the state of the legislative proposals in April 2014. Although crucial elements of the regulations are still subject to political debate, one thing is clear: the regulations will cause important changes for all companies in the field. Companies need to prepare to deal with these changes in a pro-active and timely manner to avoid having certificates suspended or revoked because they were unable to comply with the new legislation in time.

The scope of the MDR

The MDR proposal will feature a significantly extended scope. The Commission sought to remedy procedural issues with borderline classifications by providing a centralized classification mechanism and a flexible list of devices (the Annex XV list) that may not have a medical intended purpose, but will be regulated as medical devices nonetheless. The list currently includes contact lenses, cosmetic implants and invasive laser equipment. The Commission also proposed to include products manufactured utilizing non-viable human tissues or cells, or their derivatives, closing a long-standing regulatory gap. Finally, the MDR absorbs the current Active Implantable Medical Devices Directive, bringing active implantable devices into its scope. The only remainder of the old AIMD will be that its accessories, in contrast with other medical devices, will be in the highest risk class by default.

As a consequence of the proposed changes in the IVDR proposal, the definition of medical device is expanded to include devices with 'indirect medical purpose' and devices for the purpose of 'prediction' of disease. The extension of the scope to include devices with indirect medical purpose is expected to create a lot of borderline problems with devices that are intended for general health (as opposed to medical) purposes. The European Court of Justice recently cautioned against a too wide interpretation of the concept of 'medical', as this would have the unintended effect of bringing a large number of health related devices under the Medical Devices Directive.[1] It is expected that the new definition would have a significant impact on (self-) quantification products and services in the field of health related parameters, turning many of these into medical devices.

The definition of accessory will change to incorporate devices that 'assist' a medical device. The European Parliament (EP) proposed that accessory should only assist the medical intended use of the device, not its functioning as intended in general.

The changing role of notified bodies

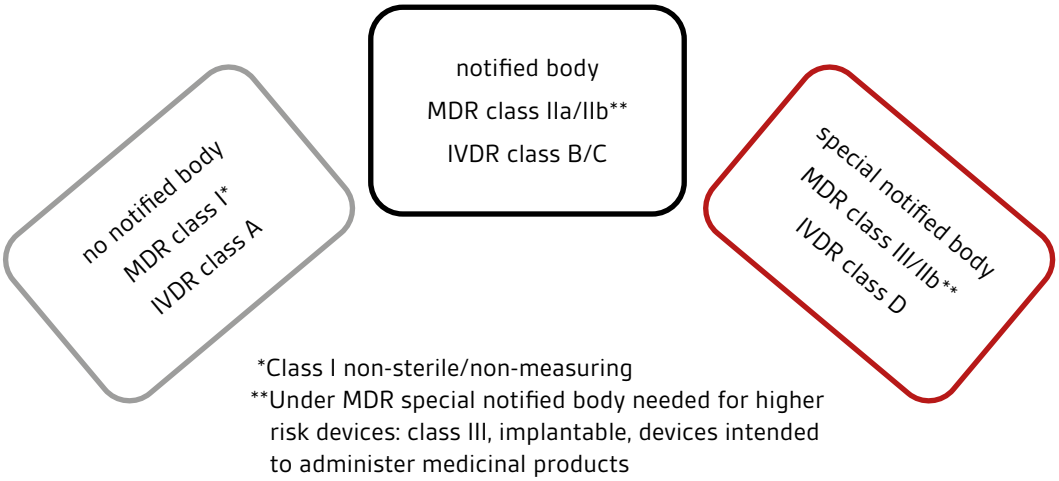
Notified bodies are expected to partly reinvent themselves under the new regulations. Not only will they need to employ much more expertise directly as opposed to contracting it in, they will also play a role in enforcement by means of conducting unannounced inspections of manufacturing processes and taking on a supporting role in vigilance follow up.

The regulations propose new accreditation requirements that only a minority of notified bodies are currently able to meet. Some notified bodies have already decided to cease activities or allow themselves to be acquired by others as a result of the member states' increased accreditation requirements under the European Commission's Joint Immediate Action Plan.[2]

1 See case C-219/11 Brain Products vs. BioSemi; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62011CJ0219:en:HTML

2 http://europa.eu/rapid/press-release_IP-13-854_en.htm

Figure 1 — Notified body competences



Under the current proposals, a category of special notified bodies will be created and only notified bodies in this category will be allowed to certify high risk devices (see Figure 1).

As a result of the changes, manufacturers may well be confronted with a forced change of notified body when the regulations enter into force, either because their notified body ceases activities or because it is not accredited as a special notified body.

As of January 2014 notified bodies are required to conduct unannounced production audits at least once every three years and more often for high risk devices, frequently non-compliant devices or in case of suspected non-conformities.[3] The unannounced audit involves a check of a recently produced adequate product sample for its conformity with the technical documentation and with legal requirements as well as a file review. This includes verification of the traceability of all critical components and materials and of the manufacturer's traceability system.

Manufacturers must be able to accommodate an unannounced audit, and so should their critical subcontractors or crucial suppliers. This means that the manufacturer must ensure they know when its critical subcontractors or crucial suppliers are producing for them; subsequently the manufacturer must communicate this to the notified body. That means that many manufacturers will need to amend their contracts with their subcontractors and suppliers.

What effect will this have on the market access mechanism and design requirements?

The market access mechanism is the most hotly debated item in the proposals. Industry fears a slow and costly 'pharma-like' mechanism and is afraid of losing the short time-to-market provided under the current system. The EP, and even more so its Environment, Public Health and Food Safety (ENVI) committee, have been advocating the strictest possible procedure for 'innovative' products via the European Medicines Agency (EMA), regardless of the fact that breast implants and metal-on-metal hip implants that caused the political concern[4] were not particularly innovative devices at all. This has resulted in a very polarized debate about the right choices that do justice to both patient safety and innovation. This has resulted in a proposed procedure (see Figure 2) with a strong emphasis on provision of clinical data in the pre-market phase, like in the medicinal products approval process.

3 See COMMISSION RECOMMENDATION 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices, which triggers application of the unannounced audits chapter in the Notified Bodies Code version 3.0; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF

4 European Parliament Committee on the Environment, Public Health and Food Safety Press Release, 'PIP Breast Implants: Learn the Lessons of This Fraud', 25 April 2012; http://www.europarl.europa.eu/news/en/news-room/content/20120423IPR43732/html/PIP-breast-implants-learn-the-lessons-of-this-fraud

Metal-on-metal hip implant

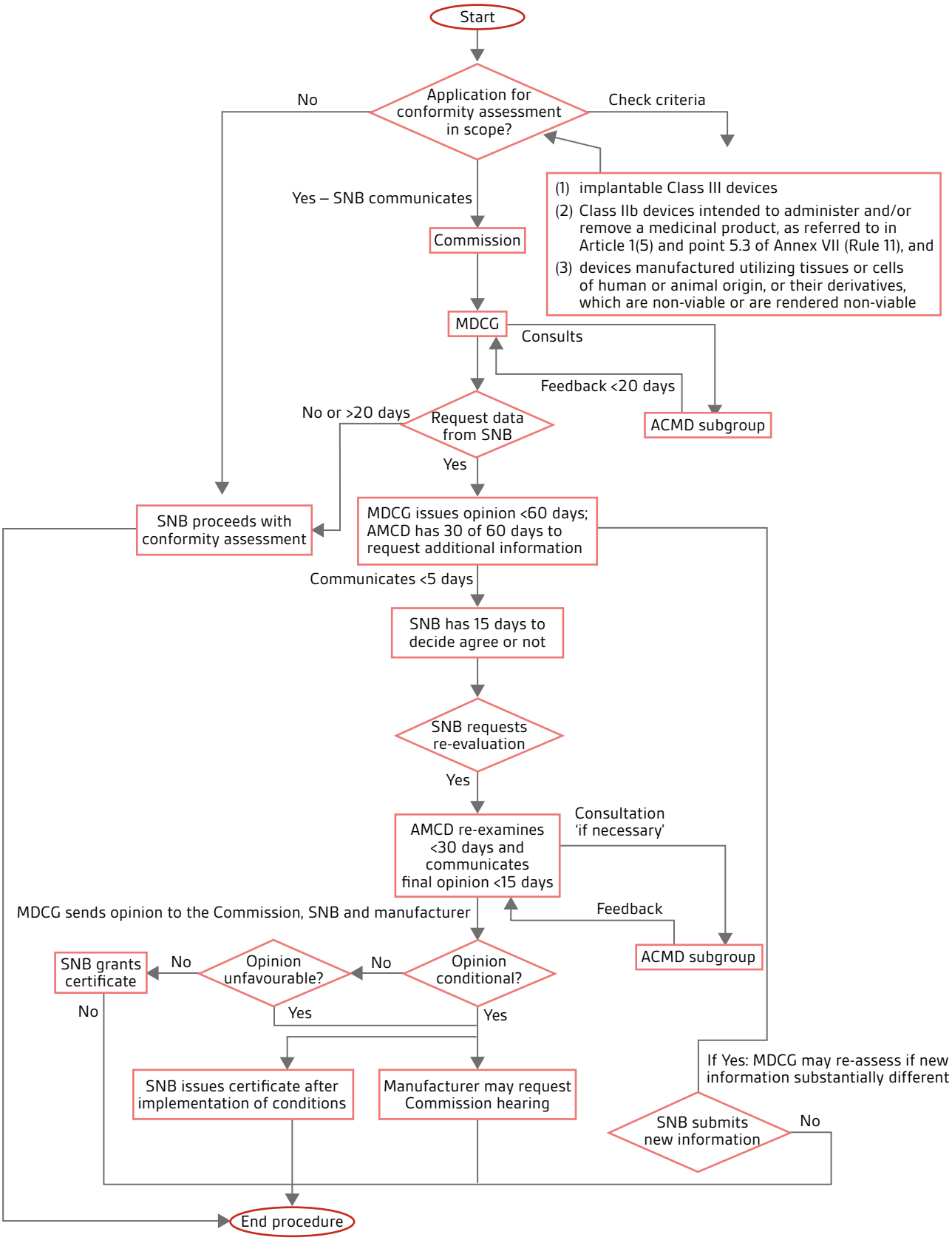
However, the European Medicines Agency (EMA), United States Food and Drug Administration (FDA) and other medicine approval bodies have in the meantime begun to question the benefits of the 'frontloaded' approval process for medicinal products.[5] The EMA will explore making its approval process less frontloaded by shifting emphasis to the post-market phase, as currently already happens with medical devices under the supervision of notified bodies and competent authorities. In the European Council meeting on 10 December 2013 member states argued that a more frontloaded approval process will not remedy the problems of deliberate fraud (PIP breast implants) nor those of problems that only come to light after significant years of use of a device in large populations (metal-on-metal hip implants), which are precisely the two issues that are used by politicians to argue that a 'stricter' pre-market approval process is necessary. Both of these issues are already addressed in the Commission proposals with increased market surveillance and increased (clinical) post-market requirements for devices. Also, member states have requested that their notified bodies pay closer attention to products in the post-market phase. There is no agreement between member states on what the market access procedure should look like however, and it remains to be seen what the final procedure will turn out to be. It is still likely that for selected innovative high risk devices some form of centralized market oversight on top of the manufacturer's notified body will be put in place.

The impact on own brand labelling

The new regulations are expected to impact the own brand labelling industry severely, because each manufacturer will be obliged to have a full technical file available for the authorities. The current legislation only requires an abbreviated technical file that refers to the technical file of the underlying original device to be available for the authorities.

5 Eichler HG, Oye K, Baird LG, Abadie E, Brown J, Drum CL, Ferguson J, Garner S, Honig P, Hukkelhoven M, Lim JC, Lim R, Lumpkin MM, Neil G, O'Rourke B, Pezalla E, Shoda D, Seyfert-Margolis V, Sigal EV, Sobotka J, Tan D, Unger TF, Hirsch G, 'Adaptivelicensing: taking the next step in the evolution of drug approval', 91(3) ClinPharmacolTher. (2012), pp. 426 etsqq

Figure 2 – 'PMA-esque' procedure proposed by EP



ACMD Assessment Committee for Medical Devices
PMA Pre-Market Approval

Reprocessing

The Commission proposal considered companies reprocessing of single-use devices as manufacture of new devices so that the reprocessors must satisfy the obligations incumbent on manufacturers. The Commission proposed that reprocessing of single-use devices for critical use (e.g. devices for surgically invasive procedures) should, as a general rule, be prohibited. Member states think very differently about reprocessing, which was clear again in the 10 December 2013 Council meeting on the MDR proposal. Given these concerns of member states, the Commission proposed that they retain their right to maintain or impose a general ban on this practice in their country. The EP is much more in favour of reprocessing, and proposed a system that presumes all devices are reprocessable unless they are placed on a list maintained by the Commission.

It is clear that there is still considerable political disagreement about what an EU regime for reprocessing should look like. Consequently, it is very difficult to predict the outcome. It is likely that reprocessing in one form or another will be permitted because otherwise member states that already allow it and have had a good experience of it (as Germany says it has[6]) would need to prohibit it. Given the resistance of other member states, it is also very likely that national prohibitions or additional requirements may be imposed.

Where does this leave the clinical and regulatory environment?

The MDR aims to elaborate on the current clinical investigation requirements in Article 15 MDD and Annex X, and align the MDR with the clinical trials regime for medicinal products. The system proposed for clinical investigations is therefore similar to the current system for medicinal products under the Clinical Trials Directive (Directive 2001/20/EC), including notification in a centralized database as is currently the case in EudraCT, the European Clinical Trials Database. While the Commission initially proposed member state authority assessment of clinical investigations, the EP proposes to have this done by ethics committees.

The MDR proposal will make Post-Market Clinical Follow-up (PMCF) mandatory as part of the clinical evaluation cycle for the device concerned, essentially implementing the PMCF MEDDEV.[7]

The MDR clinical investigation regime has been a hotly debated issue throughout its legislative history, with the ENVI Committee and EP taking the position that medical devices clinical investigations should be similar to medicinal products clinical trials. This has provoked criticism from industry that the medicinal products trial design is mostly inappropriate for medical devices.

In the legislative process important concepts have been introduced that are inconsistent with the current Good Clinical Practice standard for medical devices, the MDD harmonized EN ISO 14155:2011.[8] For example, the proposed definition of 'sponsor' under the MDR is far wider than under EN ISO 14155:2011. It is not clear at this moment if and how the EU legislation will reconcile the proposal with the International Standard. From a perspective of international harmonization and innovation, inconsistencies between the International Standard and the MDR would be undesirable as it would make the EU a less attractive place for clinical investigation.

At this point it is safe to say that requirements for clinical evidence will increase substantially and will require significantly higher investment from companies. Companies will also need to invest in employing staff who are knowledgeable in regulatory affairs, Good Clinical Practice (GCP) and clinical investigation design in order to work with and interpret clinical studies, but also to communicate with authorities and notified bodies and to meet the requirement of having a person responsible for regulatory compliance.

With a view to increasing the level of regulatory awareness in companies, the proposals oblige companies to have available in their organization at least one 'person responsible for regulatory compliance'. This requirement will apply to all companies and authorized representatives, no matter what their size; the only exception made is for manufacturers of custom-made devices who are micro-enterprises.[9] This 'responsible person' must meet the

6 German representative in the EPSCO Council Meeting of 10 December 2013

7 MEDDEV 2.12/2 rev. 2 Post Market Clinical Follow-up studies, January 2012; http://ec.europa.eu/health/medical-devices/files/meddev/2_12_2_ol_en.pdf

8 EN ISO 14155:2011 *Clinical investigation of medical devices for human subjects – Good clinical practice*

9 The concept of micro-enterprises is defined by Commission Recommendation 2003/361/EC, OJ 2003 L 124/36; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF

qualification requirements set out in the regulations and is among other things responsible for management of technical files and Declaration of Conformity and for reporting obligations. The regulation is not explicit about whether the person must be employed or can be a consultant, nor is the regulation specific about whether the person must be available full-time. Companies will need to start identifying persons in their organization or external services providers that could fulfil this role.

The new regulations concerning in vitro diagnostics

The IVDR shares the majority of its new features with the MDR proposal. There is so much overlap that the Commission considered integrating the proposals into one text, but decided against it because of the different nature of the devices concerned. Apart from the new elements shared with the MDR proposal, like the new supply chain regime and a central database EUDAMED, there are four major developments in the IVD field:

1. It is likely that the scope of the concept of in vitro diagnostic devices will be extended considerably to cover 'lifestyle tests' by including the elements of 'indirect medical purpose' and 'prediction' in the definition. This is a direct consequence of seeking to include 'nutrigenetic tests and lifestyle tests', which are not covered by the current IVD Directive. According to the EP's explanation, these 'may have at least indirectly very severe consequences to people's health' because they can pose a 'severe health threat if the test is not really of high quality and does not deliver the results it claims'.[10] However, the very imprecise criterion of 'indirect medical purpose' is expected to cause significant borderline problems with general health related tests.
2. IVDs will no longer be subject to the list-based system currently in the IVD Directive but to the risk classes developed by the Global Harmoniztion Task Force (GHTF), dividing the landscape of IVDs into risk classes A (low risk) to D (high public and high patient risk) with seven classification rules (see Figure 3).

Antibiotic susceptibility testing plates
Major changes to IVD classification will turn the IVD world upside down.

10 Report on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices, A7-0327/2013, (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)), p. 195;
http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2013-0327&language=EN

3. Connected with the introduction of the risk classification, there is the adaptation to the conformity assessment route for IVDs that do not fit any of the other classification rules. Under the IVD Directives such IVDs fall into the category that can be self-certified, but under the IVD Regulation these IVDs will need to be certified by a notified body because they end up in class B rather than A (see Figure 3 – Risk classification). Combined with the new risk classification methodology this will lead to a quantum leap increase of IVDs that require notified body certification compared to the current situation (see Figure 4).
4. Clinical performance studies will be required: IVD manufacturers will be required to produce significantly more clinical evidence for their IVDs. The IVD Regulation will provide for a regime regulating the conduct of interventional clinical performance studies and other clinical performance studies where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies. The regulation of clinical performance studies largely overlaps with the clinical studies regime in the MDR proposal.

With a view to generating the clinical evidence, manufacturers of IVDs currently on the market have to plan well, as the transitional period of five years for IVDs already on the market proposed by the Commission may well be shortened to three years following an EP proposal. In these three years the manufacturer needs to complete the required clinical studies and conformity assessment by their notified body.

Manufacturers with IVDs on the market should assess what clinical evidence will likely be required, how long it will take to generate this and plan ahead for notified body slots for conformity assessment.

Figure 3 – Risk classification

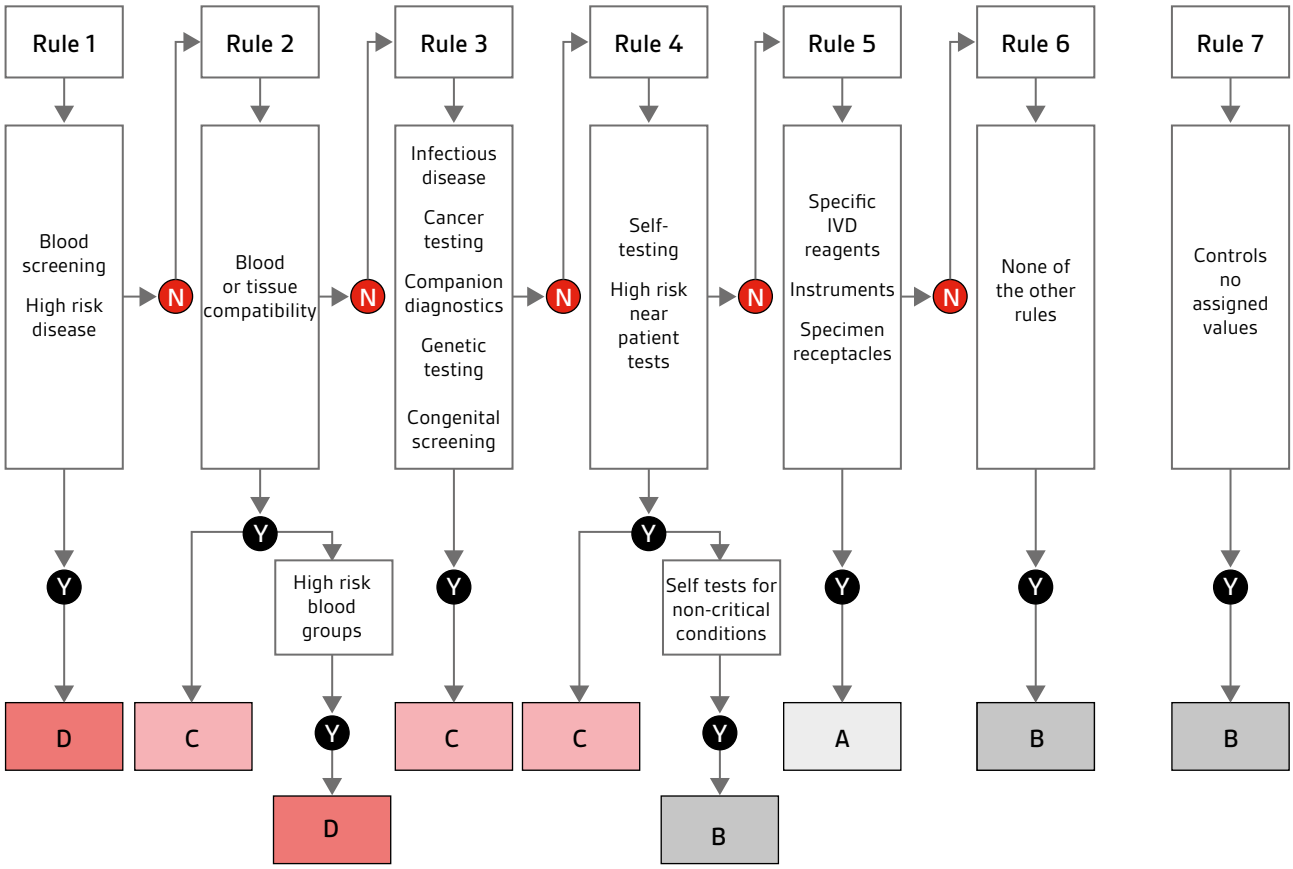
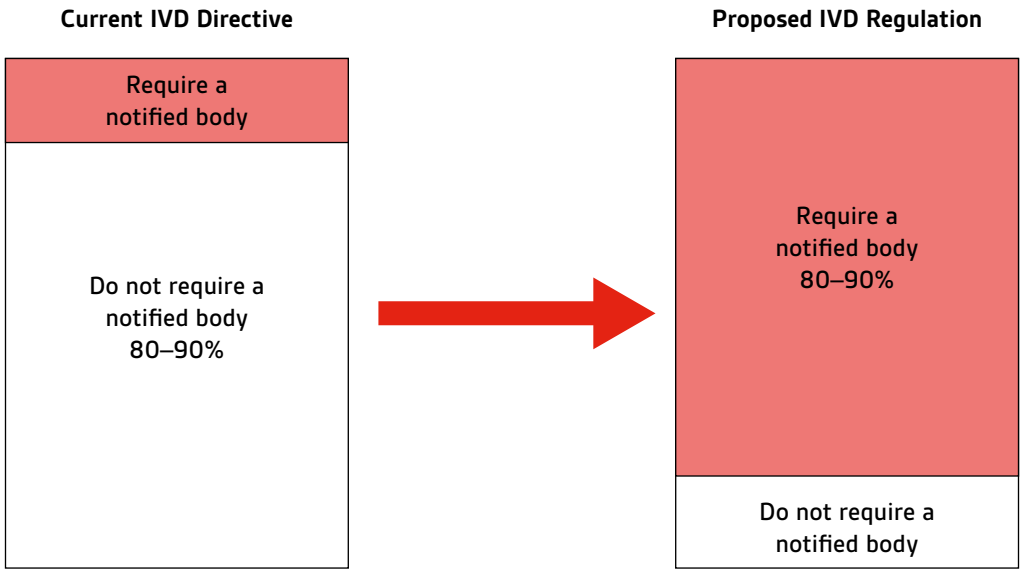


Figure 4 – Quantum leap of IVDs needing notified body certification



The increasing requirement for vigilance and market surveillance

As a prelude to the regulations and prompted by the European Commission's Joint Immediate Action Plan to deal with shortcomings in market supervision,[11] competent authorities have already started to increase their market surveillance activities. The proposals will introduce the following:

1. Incorporation of the vigilance system as described in MEDDEV 2.12 Rev 8 in regulations, including definitions such 'incident', but will also introduce new concepts such as 'serious incident' and 'withdrawal'.
2. Vigilance reporting of serious incidents and corrective actions in an EU portal that is part of the overall European Databank on Medical Devices (Eudamed) system. The portal will automatically forward the information to the national authorities concerned. The EP would like to give the public and healthcare professionals a degree of access to the vigilance and market surveillance activities logged in the database, for example to compare vigilance data on different devices. Also, the EP has proposed that manufacturers must report any incident, which will be a lot of extra work for manufacturers. Also, the authorities must evaluate all these reported incidents, and, if the EP proposal is adopted, involve patients' and healthcare professionals' stakeholder groups. The member states will need to dedicate significantly more resources than they currently do for evaluation of reported incidents. The question is whether the member states will be able to free up the resources for this.
3. Periodic safety reports will need to be filed at least once a year during the first two years after the device has been placed on the market for the first time by manufacturers of Class III devices, if the EP proposal is accepted. These reports will be evaluated by the Medical Devices Coordination Group (MDCG), consisting of member state experts.
4. A coordinating authority will evaluate the same or similar incidents that have occurred, or where a corrective action has to be taken, in more than one member state. Under the current MEDDEV a manufacturer may request this, but in practice member states are reluctant to cooperate under the supervision of a coordinating authority.
5. Member states will be obliged to coordinate their enforcement activities and draw up 'strategic surveillance plans' covering their planned surveillance activities; the Commission may recommend changes to the plans. The member states will cooperate using the electronic system on market surveillance provided by the Commission.
6. A binding procedure will be set up for dealing with non-compliant and compliant devices, both in national and cross-border situations. The Commission will function as an arbitrator between member states with respect to provisional measures taken.

11 http://europa.eu/rapid/press-release_IP-13-854_en.htm

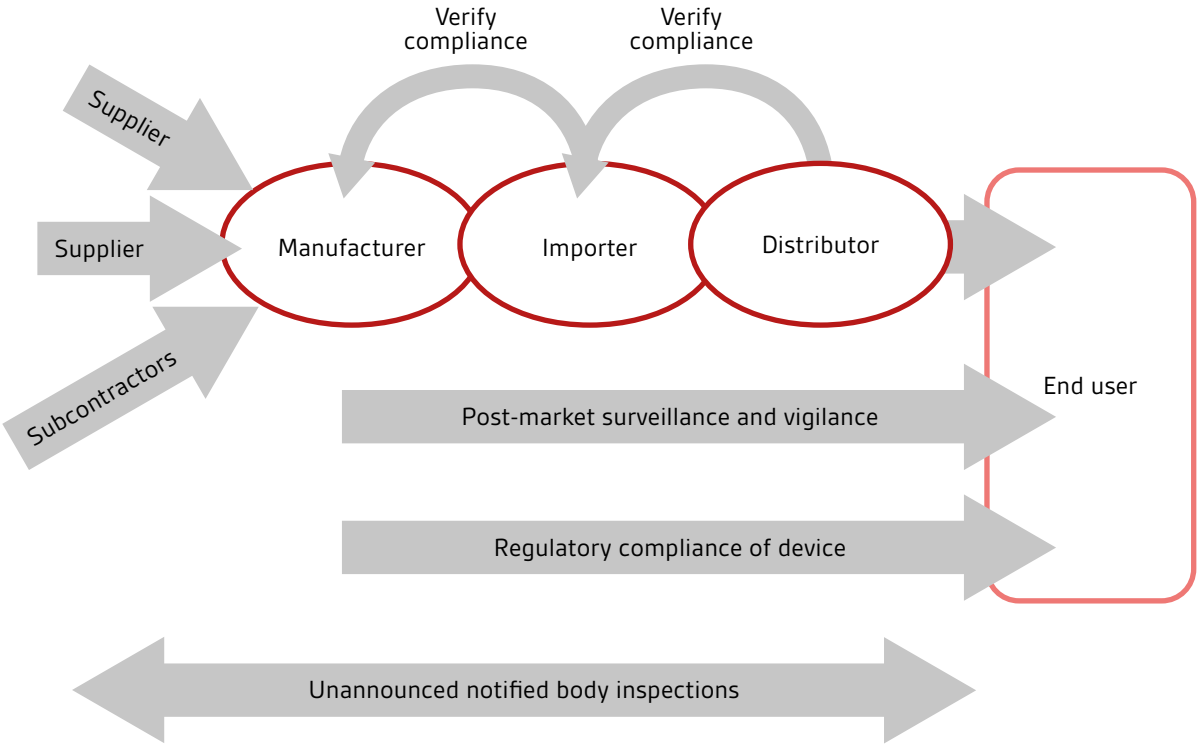
The provisions on market surveillance certainly have the advantage that there will be EU-established binding standard procedures. On the other hand, it is expected that many member states will not be able to commit the resources that the implementation of the vigilance and market surveillance procedures will require. These provisions will only work if medical devices market surveillance becomes more of a (political) priority at member state level. Companies will need to review their internal vigilance and post-market surveillance processes to prepare to scale for the increased reporting requirements.

Supply chain regulation

The MDR and IVDR will feature a new supply chain control regime according to the method set out in EU decision 768/2008 regarding New Approach regulation and follows several product areas that were already updated to this method. This new method introduces the following important changes compared to the current situation, which requires companies to amend supply and distribution related Standard Operating Procedures (SOPs) and contracts:

1. Each actor in the supply chain downstream from the manufacturer must independently verify compliance of the previous actor.
2. Each actor becomes responsible for implementing vigilance, notifying authorities of non-compliant devices and taking corrective action if required (see Figure 5). As a result, the current responsibilities in the supply chain for medical devices will change considerably, and companies will need to reflect this in their distribution contracts.
3. Manufacturer contracts need to be amended to account for the possibility of an unannounced audit at critical subcontractors and crucial suppliers.[12]
4. All economic operators must be able to identify as a matter of traceability (a) to whom they have supplied a device; (b) any economic operator who has supplied them with a device; (c) any health institution or healthcare professional to whom they have supplied a device. They must have this information available for a period of at least five years after the last device covered by the Declaration of Conformity has been placed on the market.

Figure 5 – Supply chain compliance dependencies



12 These requirements are set out in the Recommendation on unannounced audits, Annex III (Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices, OJ 2014 L253/27); http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013H0473&qid=1396003043182&from=EN

Unique device identifier (UDI) will be introduced and the importer will be responsible for ensuring that the device is assigned a UDI by the manufacturer. Currently the MDR and IVDR do not contain much more than placeholders that allow the Commission to set up an entity that will operate assignment of UDIs in accordance with yet to be defined standards and adopt delegated acts to regulate details of the system. The system will be phased in gradually, highest risk devices first. UDI as a topic will be covered in a later BSI white paper.

A look at the future

If the MDR will be in force for approximately 25 years plus, like its current predecessors, future-proofing is an important issue. Just look at the rapid development of medical devices during the life span of the current rules since 1990! In our view, the MDR proposal is too much focused on regulating 'traditional' medical devices and not well enough equipped to deal with new technological developments. While the MDR and IVDR proposals address 'devices as service' provided via the internet succinctly, software related issues such as compatibility, interfacing standards and security are not addressed in any detail.

Rapid developments in 3D printing make it possible to print custom-made devices such as orthopaedic implants and artificial veins; yet, the MDR proposal's explanation states that while

> *'manufacturers of medical devices for an individual patient, so called 'custom-made devices', must ensure that their devices are safe and perform as intended, [...] their regulatory burden remains low.'* [13]

The EU legislator still seems to regard custom-made devices as a low-risk business. Or, possibly, the expectation is that for any device, design related risks are automatically controlled by the fact that the device is made in accordance with the specifications in the prescription.

Transitioning

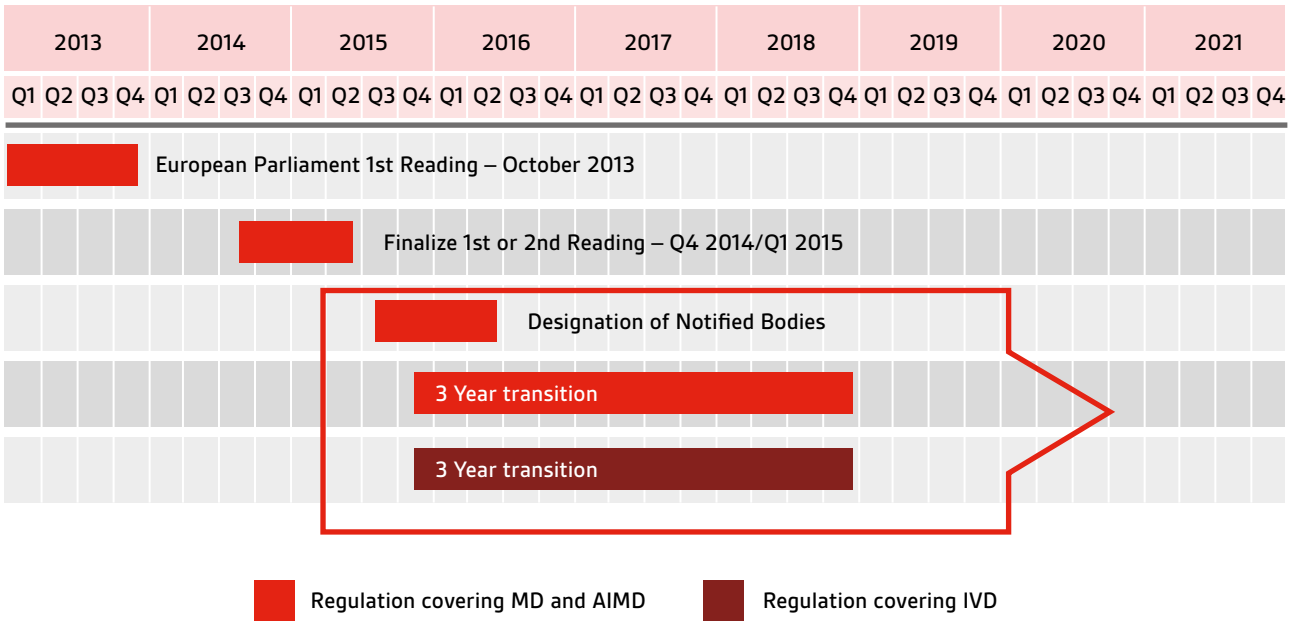
The last two important iterations in the legislative process are the EP's plenary vote on 22 October 2013 and the Council's discussion of the MDR proposal with respect to reprocessing and market access mechanism. The Parliament's plenary vote has in the meantime been voted on in a formal first reading by the Parliament on 2 April 2014, to fix the proposal and force the Commission and the Council to move forward on the dossier; the first step will be the formal response of the Commission in four to five weeks. At the Council meeting it became clear that regardless of the diligent work in the Council's working groups in the background, the member states still differ considerably in opinion on these main themes in the MDR proposal. The member states' positions are also very difficult to reconcile with the EP's proposal, and some of the member state representatives have stated during the debate in the Council that the approach of the EP is fundamentally flawed. The IVDR proposal has not been debated publicly yet in the Council. The Council is not under a deadline at this stage in the procedure, and as yet has not started to negotiate with the EP with a view to reaching a compromise text. The current expectation is that the member states will not reach a compromise with the EP before the European elections in May 2014 and that the trialogue between the Commission, Parliament and Council will not begin before early 2015. The elections may well reshuffle the political landscape, which leaves a lot of insecurities about the legislative projects of MDR and IVDR post-elections (see Figure 6).

Many important elements of both regulations still have to be filled in by means of so-called implementing and delegated acts, new EU regulatory instruments that the Commission is delegated to implement to supplement EU law. For example, the UDI system is still largely unclear and has to be shaped in delegated acts. However, the delegated and implementing acts can also impact companies directly, for example if their product is classified as a medical device or placed on the Annex XV list. It is currently still unclear whether EU law provides for legal recourse by private parties against delegated and implementing acts.

It is a widespread misunderstanding that the entry into force of the new regulations will not affect devices already on the market. The regulations will not allow grandfathering, and therefore all devices currently on the market will need to be re-evaluated and certified under the new regulations when the existing certificate under the current directives

13 COM(2012) 542 final, 2012/0266 (COD) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, p. 6; http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

Figure 6 – Timing



expires. Certificates issued after the entry into force of the new regulation will be valid until two years after the date of entry into force. This means that manufacturers will need to carefully plan ahead for the transitioning of their devices to new certificates. Where this involves their notified body, they should discuss and plan notified body capacity well ahead in order to avoid certificates expiring and having to take devices off the market until a new certificate can be obtained.

What needs to be done and when?

What will companies need to do, and when? All companies must plan and prepare for the new rules because EU law does not allow grandfathering of devices, so every device must have been certified under the new rules in the transitional time frames provided. This means that companies must:

1. Invest in qualified persons to function as 'person responsible for regulatory compliance', or appoint qualified persons already in their organization, who may need additional training for the tasks required of that person.
2. Plan and budget for the changes. This will not only involve internal analysis of technical documentation, quality system, SOPs and amendment of contracts, but also making a gap analysis and drawing up of a transition plan for all devices on the market. Companies will need to take into account that notified body slots for conformity assessment will be scarce during the transitional period. Not having obtained a certificate under the new rules before the end of the transitional period will mean taking the product off the market until a certificate is obtained.
3. Identify what (additional) clinical data will be required for their medical device or IVD and start to generate that data. Waiting until the transitional period starts may well put the manufacturer in a squeeze if the clinical evidence is not available in time for conformity assessment by the notified body, and they may need to take the device off the market until a new certificate has been granted.

BSI is grateful for the help of the following people in the development of the white paper series.

Authors

Dr Gert W. Bos, Head of Regulatory and Clinical Affairs of BSI Medtech, Head of Notified Body at BSI Germany (NB0535).

Gert has 21 years of experience in life sciences (devices and pharma), in university, industry as well as in four notified bodies. He is President of the Notified Body association TEAM-NB, Vice-Chair of the Medical Notified Body forum NB-Med in Brussels, and participates in the Notified Body Recommendation Group (NBRG), the Clinical Investigation and Evaluation Group (CIE), Medical Device Expert Group (MDEG) and the MDEG working groups on animal tissue, on MRA's, e-labelling, EUDAMED and on IVDs. He is one of the regulators representing Europe in the IMDRF working group on regulated product submissions. He is a board member of the Dutch RA Chapter.

Erik Vollebregt, Partner, Axon Lawyers

Erik is a lawyer specializing in EU legal issues relating to medical devices. He has wide experience in life sciences legal and regulatory matters, at both the EU and Dutch level. Vollebregt was trained as an intellectual property and competition lawyer. He has gained experience in contentious matters, commercial contracts, and transactional work at the Directorate-General for Competition of the European Commission and several international law firms. He is a prolific writer and publishes in life sciences legal and regulatory journals and books on a wide variety of life sciences related subjects. He is also author of the acclaimed Medicaldevicelegal.com blog about EU medical technology regulation.

Expert Reviewers

Sabina Hoekstra-van den Bosch, Senior Manager Standards & Regulations, Philips Healthcare

Sabina joined Philips Healthcare in 2011 after an extensive career as pharmaceutical and medical device regulator in the Dutch government, in which she has represented the Netherlands in several EU and international working groups. In her present role, she is also acting as Vice-Chair EU Regulatory Affairs Focus Groups of COCIR (European trade association for the Radiological, Electromedical and Healthcare IT Industry), Chair of Chapter Netherlands-Flanders of RAPS (Regulatory Affairs Professional Society) and Member of the Content Committee for Europe and Faculty Chair for medical devices of DIA (Drug Information Association).

Paul Brooks, Senior Vice President, BSI Product Services, Healthcare

Paul leads BSI services for the medical device sector in North America. He was Head of Notified Body for BSI's Medical Devices Group from 1998 to 2002. Today Paul is located in BSI's Washington DC office and is responsible for leading BSI activities in the medical devices sector including CE Marking and interfacing with US FDA. Paul is a long standing member of the American Society for Quality Biomedical Division and was a Board Member of Regulatory Affairs Professional Society (RAPS) 2008–2014.

BSI Medical Devices White Paper Advisory Panel

David Cumberland, Consultant Interventional Cardiologist and Medical Director, Prince Court Medical Centre, and Consultant at the National University Hospital, Kuala Lumpur, Malaysia.

David has specialized in cardiovascular intervention since its beginnings in the late 1970s. He was a consultant at the Northern General Hospital in Sheffield, UK, with a private practice in London for many years. From 1988 to 1994 he was Consultant in Cardiovascular Studies at the San Francisco Heart Institute, and from 1994 to 2000 was Professor of Interventional Cardiology at the University of Sheffield. He is a Fellow of the Royal Colleges of Radiologists, Physicians (Edinburgh) and Surgeons; also of the American College of Cardiology and the European Society of Cardiology. He has been a regular clinical reviewer for BSI for the last eight years.

Leo Eisner, Principal Consultant of Eisner Safety Consultants.

Leo's firm specializes in helping clients through product safety, international regulatory and quality system processes. Leo is a Notified Body Auditor for NEMKO (previously for NSAI & TÜV PS). Leo is the convener of IEC SC62D JWG9 (IEC/ISO80601-2-58) and a committee member of US TAG for TC62, SC62A and SC62D. Leo is a registered professional engineer in safety and has 28 years' experience in product safety. Leo is a member of RAPS, AAMI, ASQ, and IEEE. He is manager of the LinkedIn discussion group IEC 60601 Series – Medical Electrical Equipment.

Duncan Fatz, Independent Healthcare Consultant and writer specializing in medical devices.

As a clinical trials coordinator for the UK's North West Thames Health Authority, a researcher for the Medical Research Council and independent consultant and lecturer, Duncan has been guiding medical device companies and their products through the clinical trial process and on to subsequent reimbursement approval in the major European markets for almost 20 years. He has written two reports on conducting medical device clinical trials for PJB Publications, and two courses for Informa Healthcare.

Navin Nauth-Misir, Regulatory Affairs Professional.

Navin is Director of RA and QA for an IVD company in Wiltshire. He has 30 years' experience with medical devices and IVDs starting in the NHS. Navin worked for the UK Competent Authority investigating incidents involving critical care devices and IVDs and also as a compliance inspector. He moved to a global medical devices manufacturer where he was responsible for Quality Assurance, Regulatory Affairs and international product registration. Navin is a member of the Regulatory Affairs Professional Society (RAPS) and is also involved in the development of national and international standards. He has considerable experience working with national and European trade associations.

Mike Schmidt, Principal Consultant and owner of Strategic Device Compliance Services (www.devicecompliance.com).

Mike is a Visiting Lecturer/Honorary Academic for the Medical Device Design Masters Degree Program at the University of Auckland, New Zealand, has held the position of Secretary for IEC Subcommittee 62D since 1997 and has been a technical expert and working group convenor in the IEC since 1992. Mr Schmidt is currently the Co-Chair of the AAMI Electrical Safety Committee.

Amie Smirthwaite, Scheme Manager and Product Technical Specialist, BSI Healthcare

Amie is a Product Technical Specialist and Scheme Manager with BSI Healthcare. She has been a notified body technical reviewer for 10 years, and has previously worked in both new product development and blue skies research related to orthopaedic and cardiovascular devices, and tissue engineering. She is involved in a number of medical device standards and regulatory committees, covering mechanical testing, clinical data requirements and post-market surveillance. She also delivers medical devices training for BSI, and has developed and co-authored courses in Clinical Evaluation, Risk Management (ISO 14971), Technical File Documentation, and Post-market Surveillance and Vigilance.

Forthcoming papers

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Femmena, Itoro Udofia (April, 2014)

The Digital Patient, Kristin Bayley, Laura Mitchell, Sharmila Gardner (May, 2014)

What Medical Device Manufacturers Need to Know about FDA's Unique Device Identification Final Rule, Jay Crowley (June,2014)

Post-market Surveillance (working title), Ibim Tariah (July, 2014)

Usability Engineering (working title), Edmond Israelski (August, 2014)

BSI is keen to hear your views on this paper, or for further information please contact us here
julia.helmsley@bsigroup.com

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BSI Group Headquarters
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E. cservices@bsigroup.com
bsigroup.com

BSI UK
Kitemark Court
Davy Avenue
Knowhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 (0) 845 080 9000
E: MK.customerservices@bsigroup.com
bsigroup.com

BSI Group America Inc
12110 Sunset Hills Road
Suite 200
Reston
VA 20190-5902
USA

T: +1 800 862 4977 / 703 437 9000
E. inquiry.msamericas@bsigroup.com
bsiamerica.com