



Standards Outlook 2016

# Medical devices

**bsi.**

# Introduction

**T**he medical devices industry is well accustomed to understanding that if it does not manufacture safe and effective products which comply with the applicable safety standards and regulations, the potential consequences are significant. A medical device that is not safe or effective has potentially serious consequences not only for the patient and manufacturers, but the Certification Agency who issued the safety standard certificate and, for example, the Notified Body that issued the CE certificate.

The PIP breast implant case in France and the resulting scandal is a stark reminder of what can happen when a manufacturer fails to comply with regulations. As a direct result of this case, the EU Commission issued two documents in September 2013: a regulation dealing with the designation and supervision of notified bodies and a recommendation covering notified body audits including specifically unannounced audits.

BSI occupies a unique space in that it is the UK national standards body as well as a UK-designated Notified Body. Its scope covers all three current medical devices directives (soon to be two regulations), along with capability and competencies for other global medical device regulatory jurisdictions. While manufacturers are required to have the necessary diligence to comply with regulations, we can give them the 360-degree vision, provide them the credibility needed when looking for verification of their devices' safety, as well as knowledge and access to relevant standards and regulatory information to help anticipate the future development of the industry, with the aid of BSI tools such as Compliance Navigator.

The changes to the European regulatory compliance regime from directives to regulations (expected to be published in the Official Journal in Q1 2017) are likely to have a considerable impact. With every single medical device currently on the market having to be evaluated for its suitability, manufacturers may decide that not every device in their portfolio is worth the time and expense this will take. Others may decide to pull out of some medical device markets altogether. Overall, although the industry is being given time to bed in the new regime, we are likely to see significant change as a result.

Looking a little further ahead – though great advances are already being made now – medical devices have many more opportunities

to harness the huge innovations being made in technology. Genomics – where DNA is used to target diagnoses and make better treatment decisions depending on the patient's genetic make-up – and nano-technology are two such areas. In-situ technology, where devices can be made through the multi-layering of material during actual live treatment, is another incredible advance, while in itself providing a significant challenge to how this new wave of technology will be regulated.

Responsible management of these emerging technologies is needed to ensure regulation does not limit or stifle innovation, whilst still maintaining optimised patient safety. Wearable technology worn in the form of a piece of jewellery or clothing that can assess a part of a person's health, could become part of the self-care of the future. Rather than having to wear a heart or blood pressure monitor, there could be a much more discreet way to do it. The impact this could have on the patient experience – and indeed on the wider experience and costs of effective and sustainable healthcare provision – are yet to be fully realised.

Meanwhile, there is already a debate around the use of apps and whether they can be considered – and be used as – a medical device or not. While the public continues to perceive apps as nothing more than gadgets or easily disposed of consumables, they can actually have implications for decisions a person takes about their health. There is a role here for user education around potential risks, but standards must also play a part.

Developers of such tools must understand the wider impact to public health that developing not just a disposable consumable but a medical device can have. The enormous amounts of data being generated by apps is another consideration for future standards setters and policy makers. Who will own this data? Will its potential future use be governed on a national or international level?

These and many other questions are set to be tackled by the medical devices sector. It is an industry facing the future – and BSI is there to face it with you.

Shirley Bailey-Wood, Director Information Solutions, BSI

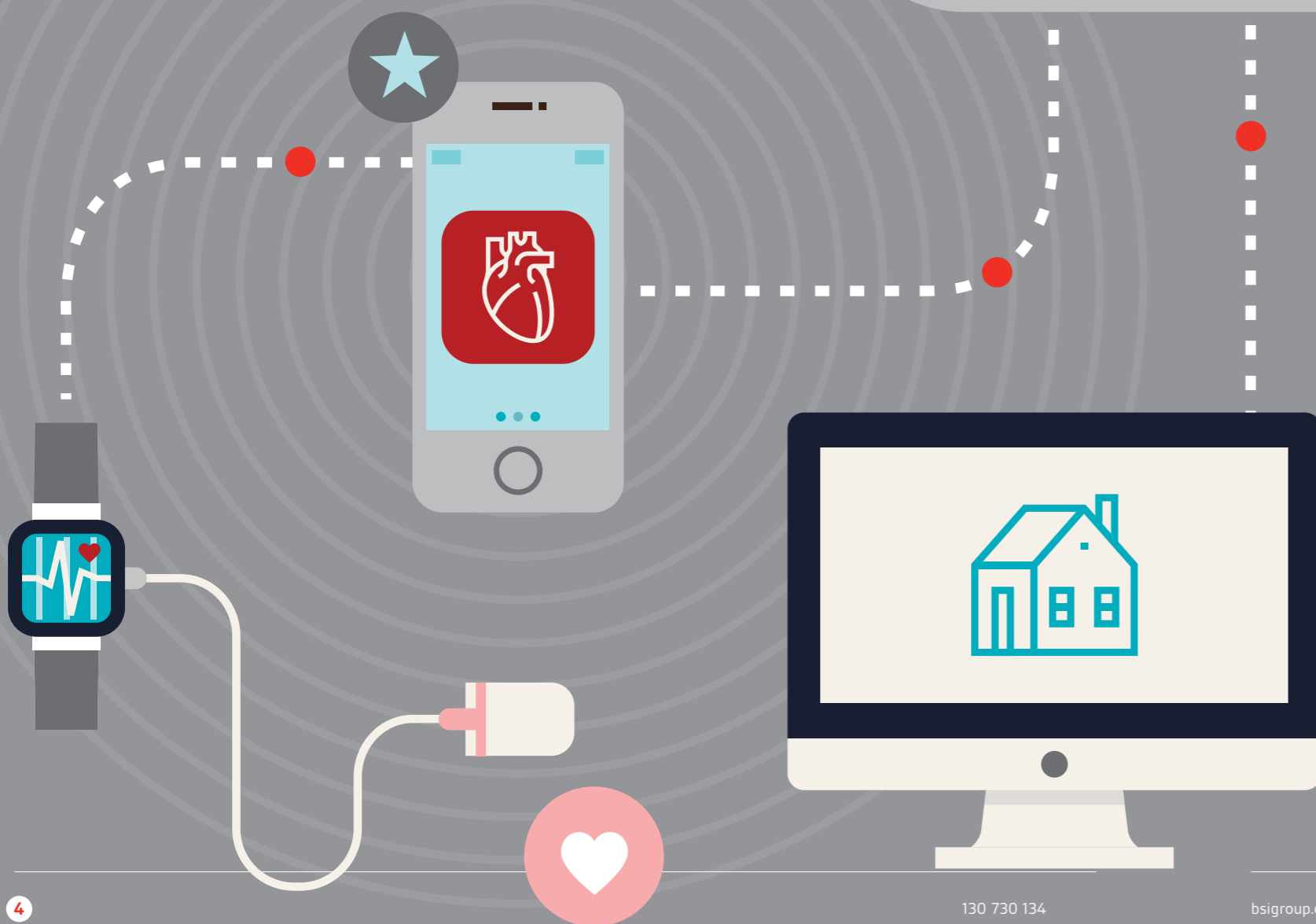
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**“ It is vital that we support manufacturers to ensure devices are brought to market which are compliant, safe and effective. ”**

# Regulatory compliance

The medical devices sector is one of the most regulated of all industries, heavily governed by regimes designed to ensure the utmost safety and effectiveness.



“Affixing a CE mark is the medical device manufacturer’s claim that a product meets the essential requirements of all relevant European directives.”

The design, manufacture and testing of medical devices all need to conform to a considerable number of applicable regulations. The regimes that govern these regulations for the EU market under the provision of the legislative framework called the New Approach Directives, come from a range of national and international standard organisations (such as BSI), while the medical device industry itself is increasingly international in ambition and scale.

While signing up to adherence with the applicable standards is voluntary, manufacturers actively choose to adopt them in their processes because to do so is a simple and efficient way of conforming with legislation. European Union (EU) directives (expected to become regulations around autumn 2016) are the most direct form of EU law, with binding legal force throughout every EU member state, on a par with national laws and are there to improve market surveillance and boost the quality of goods entering the market.

Affixing a CE mark is the medical device manufacturer’s claim that a product meets the essential requirements of all relevant European directives and this is a legal requirement. Medical devices cannot be placed on the market within Europe without a CE mark to one of the three medical device directives, even if the product is manufactured outside the EU. The only exceptions to this are devices for clinical trials – which must be labelled as such – and custom made devices, for example under the supervision of a healthcare professional for a named patient.

The three medical devices directives are: Medical Devices Directive (MDD), Active Implantable Medical Devices Directive (AIMDD) and In Vitro Diagnostics Directive (IVDD).

Equally, the circumstances in which a medical device is used may be assumed to be in a heavily regulated healthcare environment. But the rapidly increasing number of devices available for use in non-healthcare and non-regulated environments, such as the home, have led to fast-approaching changes in the way the sector is regulated.

60

The number of EU Notified Bodies that can certify to the Medical Device Directives

While manufacturers must be aware of where and how their devices will be used and design accordingly, in a bid to respond to this changing market, the EU is currently reviewing all three current medical device directives. The impact this is expected to have on the medical devices market as said directives become regulations is considerable.

Transposing the requirements of the Medical Device Directives into national law in countries within the European Union and partner countries is the role of a Competent Authority. In the UK that role is carried out by the Medicines and Healthcare Products Regulatory Agency (MHRA). The Competent Authority is also responsible for designating one or more Notified Bodies to act as independent third-party assessors of a manufacturer's compliance with directives.

There are around 60 EU Notified Bodies in total that can certify to the Medical Device Directives. Products holding a CE mark from any of these can be marketed to patients, pharmacies, clinicians and other healthcare professionals in any EU country. However, not all of these Notified Bodies can certify to all categories of medical device products.

There are key regulatory requirements to meet in the three EU medical device directives (MDD, AIMDD and IVDD). Assessment of conformity with the regulations requires an audit to be carried out on-site of the manufacturer's quality system or evidence of a current valid Quality Management Scheme (QMS) certificate from a recognised Notified Body that has comprehensively audited the manufacturing process, systems, controls, material handling, microbiological and sterile systems and so on. ISO 13485 (the international harmonised Medical Device QMS standard) is the standard explicitly put in place for medical devices quality management systems. This is then valid for three years and includes an annual surveillance audit to ensure conformity.

The manufacturer must provide all the technical documentation in support of the safety and performance claims for the device. This is then generally assessed against essential requirements set out within the EU directives against EU standards, common technical specifications and relevant guidance.

To distribute its medical devices internationally a manufacturer may also have to ensure ongoing compliance with bodies such as the United States' Food and Drug Administration (FDA), which in turn uses the standards set by the Association for the Advancement of Medical Instrumentation (AAMI) and with ASTM (formerly the American Society for Testing and Materials).

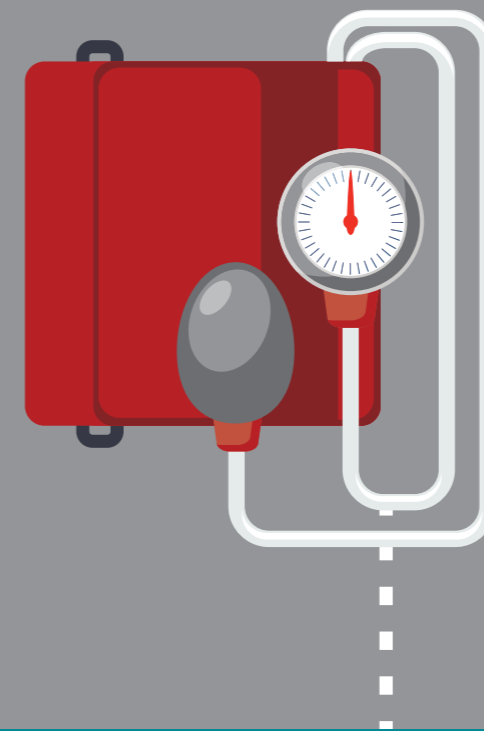
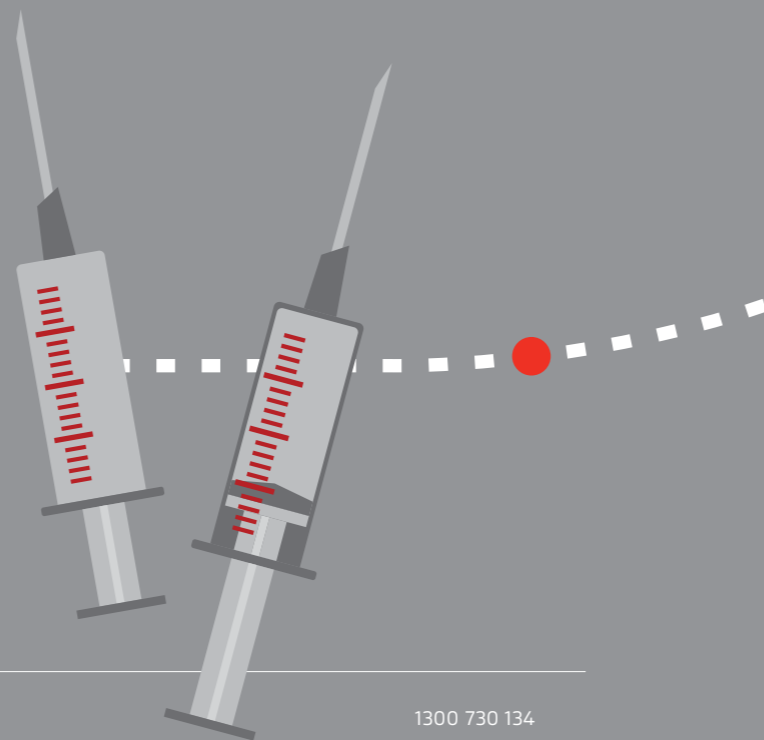
The International Medical Device Regulators Forum (IMDRF) has developed a Medical Device Single Audit Program (MDSAP) which

is currently being rolled out with a number of global regulatory authorities. BSI has recently achieved Audit Organisation Status thus permitting it to undertake audits compliant with MDSAP and being able to provide this service to manufacturers that have signed up for this program.

As a Notified Body or Certification Agency BSI is also recognised by CMDCAS (Canada), JPAL (Japan), ZLG/ZLS (Germany), TGR (under Australia CAB), Taiwan FDA (under TCP program), Hong Kong MDCO (under Hong Kong CAB), and Malaysia CAB services.

In addition BSI publishes expertly written information and guidance on international organisations' regulatory changes to help the industry better understand the standards and put them into context in the regulatory environment.

To further aid those in the sector, a series of in-depth white papers exploring issues around medical devices has recently been published by BSI. Topics have included *The growing role of human factors and usability engineering for medical devices*, *Engaging stakeholders in the home medical device market*, *What you need to know about the FDA's UDI system final rule* and *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and consequences for the market*. ●



## The classification of medical devices

For medical devices (MDDs) the route to follow for certification by manufacturers depends on the risk classification of the device Class I, Class II (a and b) and Class III.

For low risk (Class I) devices (examples include wheelchairs and bandages), the manufacturer self certifies and applies the CE mark itself. However, if the device has a measuring capability or is supplied sterile, a Notified Body is then required.

For Class IIa (low to medium risk, examples include sutures and dental fillings), Class IIb (medium to high risk, for example incubators and complex wound dressings) and Class III (high risk devices, such as drug-eluting stents, hip replacements and absorbable sutures), the manufacturer's quality system requires a favourable audit from a Notified Body to proceed to CE marking.

For Class III devices a Notified Body also evaluates the design of the medical device, by reviewing a design dossier submitted by the manufacturer, and issues a certificate

of conformity with the EU directive if it is satisfied with the device's safety and performance data.

Active implantable medical devices (AIMDs) are considered by their very nature to be Class III high risk devices and must undergo full Quality Assurance, including design of the product before it goes to market and post market surveillance once it is in use.

In-vitro diagnostic devices (IVDs) are devices and accessories used to perform tests on samples, such as blood, urine and tissue – effectively any sample which can be taken away from the human body to help detect infection, diagnose a medical condition, prevent disease or monitor drug therapies.

The IVD Directive groups IVDs into four categories according to the perceived risk associated with the relative hazard to public health and/or patient treatment by an IVD failing to perform as intended. Its classification depends on the perceived risk to the patient vs the perceived benefit of having the sample taken.

The four categories for classifying IVDs are General, Self-Test, Annex II List B and Annex II List A. Examples of General IVDs – where no Notified Body is required and the manufacturer self declares that their product has been manufactured to the appropriate standards and requirements – include tests for hormones, cardiac markers and haematology. For Self-Test IVDs – where examples include pregnancy and home cholesterol testing kits – a Notified Body is required to review its design and labelling to confirm their suitability of use.

For Annex II List B, such as testing for Rubella and the self-test for blood glucose, a Notified Body is required to carry out an audit of technical documentation and the device's quality management system. Annex II List A category devices require a Notified Body to carry out a design review and an audit of a device's quality management system. Examples of this type of device include HIV and Hepatitis ABO blood grouping testing.

# Changes happening in 2016

Considerable upheaval is expected as a result of changes in Europe's medical devices regulatory regime, with a move from European directives to regulations.

## Regulatory change and European harmonisation

From 2016, major changes will take place in Europe's medical devices regulatory regime, with a move from European directives to regulations. The move is believed to have been prompted by the European Parliament's concern that the market is becoming subsumed with too many products being rushed to consumers without thorough enough proof of their suitability for release.

Directives are addressed to member states rather than their citizens, and are therefore only legally binding upon the states themselves where the directive sets the framework but the practical details of implementation are left to the member states. When they are required to become regulations, they become binding on individuals and effectively form part of domestic law as soon as they are made. Generally it is only necessary to amend existing national provisions that may have been inconsistent rather than make new legislation completely.

And so in parallel, all 400 or so existing European medical devices standards which were created to support the directives will need to be revised. Some of these changes are expected to be minor or largely technical, while others will be more extensive.

One immediate issue is that in future all devices should feature a traceable unique device identification (a UDI), which all manufacturers, importers and distributors will be required to store

details of and which can then be called upon for checking by a Competent Authority. This move is intended to allow traceability for post-market surveillance of a device's performance.

Notably, 'in-house manufacturers' – where healthcare institutions do their own testing on site, thereby deemed to be creating a device in the process – will likely be exempt from the regulations, as this was thought to be too burdensome on the institutions in question. Regardless of this exemption, it is anticipated that some form of coding system will likely have to be put into place to allow the use of such devices to be tracked. This is an area of contention with manufacturers, who believe this market should be regulated to maintain the high standards they are expected to meet.

**“ In future all devices should feature a traceable unique device identification (a UDI) which can be called upon for checking by a Competent Authority. ”**

Another area of contention is the reprocessing of single-use devices and who should be held liable for the risk inherent in using a device more than once. Who should be responsible – the person or organisation using it, or the manufacturer of the device?

Implementation of the regulations – which are expected to be fully ratified by the end of 2017 – is being phased in in two stages. The new regulations are expected to apply to medical devices from 2019, allowing for a three-year transition, and to in-vitro devices from 2021. The five-year transition for the latter has been granted due to the significant impact the changes will have on the in-vitro devices market.

### Expected changes to the market

Market observers expect the industry to undergo considerable upheaval as a result of the regulatory changes.

With some products in future likely to take years rather than months to get to market there is a risk that some companies will question whether the financial commitment and time taken to prepare for the new regulations is worth it. Others may consolidate or be taken over by larger competitors.

Equally, a number of companies are likely to realise that to thrive in the sector, their increasing specialisation will be key. Rather than risk making expensive ventures into markets that may take years to be fully realised, it may make more sense to concentrate on market areas where they already have in-depth knowledge.

In addition, perhaps surprisingly, tried and tested, or 'legacy', products, are also likely to be among those withdrawn from the market by manufacturers. As the EU does not allow for 'grandfathering' (allowing exemption from a law or regulation for certain existing parties or products), and with it being harder to produce clinical evidence of the efficacy of a long-standing



product, it is highly likely that manufacturers will have to take commercial decisions.

Their dilemma is whether they can afford to concentrate their research and development spend bringing old products up to the new regulatory framework, or whether it is more viable for them to focus on bringing new products to market.

This is likely to affect the sector across product types, with potentially thousands of products being removed, but it is believed

it will particularly affect commodity-type items that are bought in bulk but can have numerous variations in specification. One example is surgical scalpels, that are manufactured with variations in areas such as shape, length and type of blade.

Industry observers are concerned that market consumers are not fully aware of the fast-approaching changes. It could take many years for its full impact to be realised, but a period of education during the transition period is necessary.

“ The new regulations are expected to apply to medical devices from 2019, allowing for a three year transition, and to in-vitro devices from 2021. ”

Equally, not all manufacturers will be aware of the impact that these moves will have on their legacy products and in turn the effect this could have on their device portfolios. Overall, manufacturers may be faced with less time to ensure their products meet the new regulatory requirements.

### BSI's role in changes to European Standardisation

The work of undertaking these revisions falls to the CEN (European Committee for Standardisation) Advisory Board on Healthcare Standards (ABHS), which is tasked with providing strategic advice on healthcare standardisation issues within the European Economic Area to both CEN and the European Committee for Electrotechnical Standardisation (CENELEC) and their respective technical boards.

BSI, as a leading member and contributor to CEN, is tasked with running the ABHS' secretariat. We have full-time resource located at BSI's headquarters in Chiswick, London to carry out the day-to-day administration of the ABHS secretariat. This involves coordinating the work of individual national experts on technical issues, organising the ABHS' biannual meetings, and facilitating communications.

While supporting this secretariat, BSI can gain insight as to which standards are likely to require complex revisions and which will need less intricate reworking, and this is valuable insight to relay to the industry and our medical device customer base. ●

3-5

Expected number of years before the full impact of the regulatory changes will be realised

# Beyond 2016: Emerging trends and issues

Digital technology and apps, and device-drug combinations are two fast-growing areas where BSI expects to see significant changes within the industry.



## Digital technology and apps

In just a few years, the 'apps' loaded on consumers' smartphones and tablet computers have become central to their lives, linking them to friends, family, e-commerce sites and information sources. A growing number of apps fall into the category of 'health and wellness', helping consumers carry out tasks such as tracking weight loss, following a diet regime or progressing towards exercise targets. It is estimated that there are now hundreds of thousands of such apps available to consumers, with massive future potential in the area of self-care, especially around every day health issues such as pregnancy, diabetes and mental health problems.

It is a prime example of an industry which has rapidly developed in a largely unregulated market, and with which regulators have struggled to keep pace.

Do health and wellness apps constitute a medical device? It is a grey area, albeit one with a pragmatic answer. Namely, if a consumer downloads a fitness or heart rate monitoring app for their own fitness purposes, then it isn't a medical device. But should a medical professional such as a doctor ask us to download and use the same app for medical or clinical purposes, or use it for their own medical or clinical use, then it is. Anything worn next to the skin, such as to detect heart rate or changes in a skin condition, is also considered a medical device.

To date, an estimated 50 apps have been developed specifically for use as medical devices and have had to acquire a CE mark as a result.

It is a subtle difference but a vital one. Apps are commonly thought of as consumables, something that is fun but of no real consequence. However if a consumer is making changes to their life as a result of the data produced by an app, the repercussions could be considerable.

The consequences with the use of apps specifically designed as medical devices are clearer. As operating systems can affect the calculations the app produces, using them appropriately is vital to improve outcomes for the patient.

A degree of quality assurance and how that is applied is needed, which is where standards come in.

So it is essential that software developers – who are often not traditional medical device manufacturers, or medical device manufacturers less accustomed to app development – understand an app's potential classification as a medical device.

Another considerable issue is what happens to the huge amount of personal and health-related data being generated by such apps and how this is applied – with the data protection implications entailed in this. Will it eventually be stored on a national basis or is it more sensible for it be controlled and disposed of locally by the app user? How will this be monitored – according to national or internationally determined laws?

To address the issue, new standards are becoming necessary. For example, BSI with sponsorship from the UK's innovation agency, Innovate UK, published a key document in early 2015, *Health and wellness apps – Quality criteria across the life cycle – Code of practice (PAS 277:2015)*. It represents a major step forward in setting out standards that developers should follow and aims to drive up quality as a consequence. As a code of practice, it brings together knowledge and expertise from across the medical spectrum, building on existing standards for addressing risk in software life cycle processes in medical devices. For further guidance speak with your Notified Body or Competent Authority.

That said, PAS 277 does not cover the requirements for apps that are classified as

# 50

Estimated number  
of apps developed  
specifically for use as  
medical devices

210

**days: manufacturers must work in partnership with the Notified Body to ensure conformity within this timeframe**

medical devices, nor is it a rigorous document to aid in classifying a health and wellness app as a medical device.

Rather it asks developers to consider issues such as risk analysis; what problem is the app trying to solve and what are the health and wellbeing outcomes that may be achieved by the app. Other issues to consider include what kinds of information the app is handling, scenarios describing typical use of the app and explicit limitations relating to the apps' requirements or use. Market surveillance and feedback should be considered, much as it would be with a medical device. Support and sustainability for the anticipated life of the app should also be described and planned for, as should the impact on users of discontinuing support for the app. This should be planned for.

Although intended primarily for app developers, to help them define appropriate quality criteria for app registries and app repositories, PAS 277 can also be used by health care professionals selecting apps to recommend and by providers, charities, and community organisations looking to commission bespoke apps.

There will be more to come, driven by data and technology interplays. Looking to the future, there are increasing possibilities around what apps will be able to achieve. In the area of mental health, for instance, the potential of apps that promote users to carry out mindfulness exercises or provide access to advice for common mental health problems have yet to be fully explored. Other apps could carry out physical health checks, such as assessing blood sugar or blood pressure levels or checking a user's

**“ Apps are commonly thought of as consumables, but if a consumer is making changes to their life as a result, the repercussions could be considerable. ”**

heart rate. The impact that this could have on users' self-care and their consequent use of conventional health services could be immense.

Building an evidence base is the current shortfall in this area. But if evidence can be achieved to show that an app can significantly result in better health outcomes it will be an area with enormous opportunities.

### Device-drug combinations

The area of device-drug combinations is a growing one and one of increasing concern to medical device manufacturers. Manufacturers have to be clear whether their product is a medical device or a medicinal product, in terms of classification.

If it is a medical device, it is considered a Class III device, which requires a Notified Body to issue an EC certificate of conformity with the directive to confirm it is satisfied with the device's safety and performance data. BSI has been designated by the UK's Competent Authority, the MHRA, to be the Notified Body carrying out conformity assessments on the device part of device-drug combinations; auditing manufacturers of such products and issuing certificate of conformance or non-conformance as appropriate.

Working in partnership with the relevant Notified Body working on the drug part of the combination, there is a mandatory 210-day timeline that must be adhered to. This is a challenge in the face of the manufacture of increasingly complex device-drug combinations. Working on a case-by-case basis is required.

Primarily developed by medical device manufacturers who may have limited knowledge of medicinal product regulation, medical devices is a market increasingly being explored by pharmaceutical manufacturers – and by companies from both sectors working together to develop new products.

BSI as a Notified Body must consider the following points. Does the proposed product contain an integral substance, is that liable to act on the human body, and is it a medicinal product?

If the principal role of a product is a physical one, then it is a device. And if its principal role is in delivering a drug, then it is a drug. If

the delivery of a drug is ancillary to the device itself, for example through a stent that is coated in a drug, or a wound dressing containing ionic silver, then that product is a device. However, if a device is used purely to deliver a drug – for example a torpedo device placed in an artery – then it will be classed as a drug.

It is important to note that central to being considered as a device-drug is the proposition that the combination must add value. A nicotine patch, for example, does nothing without the nicotine, so would be considered as a device-drug combination.

Equally, if a dressing is coated with a peptide, the peptide will promote healing of the wound, but so will the dressing itself. Rather than the peptide being an ancillary, it is working together with the dressing. This then is to be classed as a drug-device combination, not a device-drug combination.

This classification also means that if the principal mode of action of a drug is a physical one – for example antacids or diet pills, it can be classed as a device, even if it was never intended to be classed as one and is generally thought of as a medicinal product.

This is an area of contention amongst manufacturers. Devices are generally quicker to be able to bring to the market, as they are not obliged to undertake the kind of large scale randomised patient data trials often necessary to bring a medicine to the market. The inclusion of a drug must be justified. However, this also means devices can lack evidence of medical efficacy.

A further complication is the emergence of devices in which, although the device and the drug is in one unit, the manufacturers argue that the drug is present in such a manner that it cannot act on the human body. Unless that can be proved, it will always be assumed that the drug is liable to do so, and so Class III certification is required. Scientific data must be provided to support any claims that a drug is not liable to act, in order to avoid a Class III classification. Nor is there any room to argue that there is only a small amount of a drug in a device as there is no concept of 'amount' of a medicinal substance in the medical device regulations.

With the intention of clarifying such situations, a new proposed Rule 13 is in draft mode, with BSI providing input to the Competent

Authorities drafting the rule. In-vitro diagnostic devices, which cover anything you can take from a patient as a specimen for the purposes of diagnosis includes everything from a home pregnancy test to HIV tests.

BSI is the Notified Body for in-vitro diagnostic testing devices. As scientific and technological advances apace, the sector has seen the emergence of both drugs and diagnostic testing now available that was inconceivable when the current in-vitro rules were published in 1998. Meanwhile, disease states of interest have also changed considerably, with the emergence for instance of new-variant CJD and SARS. BSI has also acquired additional expertise in areas such as genetic testing, cancer testing and companion diagnostics (tests to predict treatment response and reactions).

90%

**Percentage of in-vitro diagnostic devices that will soon fall under the scrutiny of a Notified Body**

A forthcoming five-year transition to the new EU In-Vitro Diagnostic Regulation to replace the directive will see the current 10 per cent of in-vitro diagnostic devices that currently fall under the scrutiny of a Notified Body rise to 90 per cent. This is largely due to a new risk-based classification system replacing its current risk-based system. The majority of IVDs which are currently self-certified will in future require the services of a Notified Body to ensure their safety and performance.

The proposed changes also include extending and clarifying the scope of the IVD Directive to include high-risk devices manufactured and used within a single health institution (where hospitals do their own testing, for instance), genetic tests, those that test a person's predisposition to a genetic disease, companion diagnostics providing information to predict treatment response or reactions and medical software.

The sector has been given five years, until 2021, to transition to the new regulations, as their impact will be so considerable. ●



# Summary

Given recent events, industry insiders would likely agree with the need to raise the bar for compliance in the global medical devices arena. Standards will have an important role to play in support of the new regulations.

**G**lobal jurisdictions are implementing new or revised regulations and where no (or limited) regulatory requirements currently exist then full regulations are being established. With European Medical Devices Directives expected to become Regulations in mid-2017 a solid legal framework is set to be implemented for placing safe and effective medical devices on the market throughout the EU.

However, caution must be exercised to ensure that the degree of compliance being applied is appropriate and proportional.

The development of appropriate product or process-related standards also have an important part to play in support of the use and adoption of these regulations. Where possible, the use of internationally recognised standards should be adopted – doing so in preference to regional, national or local standards has a significant benefit for manufacturers as it restricts the number of product specifications required for each market. This supports quality and safety within an affordable manufacturing approach.

In support of this, Competent Authorities and designated Notified Bodies will in turn be subject to much greater scrutiny and monitoring.

With our standards development organisation and separate Notified Body organisation,

**“ BSI will be there to help ensure manufacturers and consumers have an effective and safe medical devices experience. ”**

BSI has a responsibility to ensure compliance with the applicable regulations while at the same time recognising other challenges, particularly around new products. The introduction of new materials and innovations in how they are applied, how these are regulated and not subject to excess burdens is another key responsibility.

This is especially key when looking ahead to the huge advances being made in medical devices technology. The potential of nano-technology and genomics in making targeted treatment clinical decisions and applying treatment is considerable. The use of in-situ technology during treatment is another advance with incredible potential.

Meanwhile, the ‘patient experience’ paramount to healthcare delivery grows steadily more influential. In an area where the possibilities are only just beginning to be fully understood and explored, there is huge potential for the capacity of healthcare apps – and even discreet wearable technology – in improving users’ physical and mental health self-care.

The impact this could have on the patient experience – and on the wider experience and costs of effective and sustainable healthcare provision – are yet to be fully realised. But BSI will be there to help ensure manufacturers and consumers have an effective and safe medical devices experience. ●

**2017**

European Medical Devices Directives are expected to become Regulations next year

# Learn more about standards



## How to get involved

Share your expertise and work with us to create the standards of tomorrow.

The knowledge embedded in the standards we publish helps organisations to improve their performance, manage risk, innovate and grow. Formalising knowledge in this way builds trust with users, consumers and industry at large, bringing benefits to the wider community. But for standardisation to work, individuals and organisations from a wide range of stakeholder groups need to be involved in creating standards.

By participating, industry experts can represent their organisations and community of interest to ensure that their requirements, understanding of the market and voice is heard and captured when standards are developed at either national, European or international level.

We actively seek representatives from many other groups including: consumer organisations; industry and professional institutions; certification, testing and inspection bodies; educational establishments; research organisations; UK notified bodies; enforcement bodies and government departments.

All participation is voluntary and there are many ways that you can get involved in developing standards, including suggesting ideas for new standards, participating in public consultation on standards or by becoming a committee member. More than 10,000 members sit on some 1,200 BSI committees.

**18,838**  
EUROPEAN  
**26,098**  
INTERNATIONAL

Number of Origins of standards published

**49,457**  
Number of standards in our current portfolio

**7,538**  
Number of standards projects in development

**1,374**  
Number of members who act as experts in an individual capacity

**11,285**  
Number of active committee members  
**1,064**  
Number of organisations the committee members come from

**1,936**  
Number of technical and sub-committees

**1,500**  
Approximate number of new experts joined in 2014 & 2015

## How BSI Standards are made

Products from BSI Standards fall into three broad categories:

- 1 Standards products (i.e. publications established by consensus and approved by BSI committees).
- 2 Non-standards products (such as guidance documents, training materials and electronic products).
- 3 Joint products (i.e. combinations of standards and non-standards).

## There are six types of British Standard:

- 1 Specifications set out detailed requirements to be satisfied by a product, material, process, service or system and the procedures for checking conformity to these requirements.
- 2 Methods provide a complete account of how an activity should be performed (and, if appropriate, the equipment or tools required) and conclusions reached, to a degree of precision appropriate to the stated purpose.
- 3 Guides give broad and general information about a subject, with background information where appropriate.
- 4 Vocabulary standards list definitions of terms used in a particular sector, field or discipline.
- 5 Codes of practice comprise recommendations for accepted good practice followed by competent and conscientious practitioners, and bring together practical experience and acquired knowledge for ease of access and use of the information.
- 6 Classifications comprise designations and descriptions of different grades of a product and identify and arranges data in hierarchical order.



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