A Mobile Device Notified Body

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Expertise and experience

Helping you stay mobile through the regulation maze

We are witnessing an explosive growth in medical devices that use wireless technologies. Some devices are implanted and some are worn on the body, to control bodily functions and to measure an array of physiological parameters. The data from these sensors and monitoring equipment together with patient observations of daily living can be transmitted wirelessly to another location for review by relevant specialists.

Such devices allow for remote management of patients with a range of chronic diseases or patients recovering from stroke, for instance. Mobile medical applications are also transforming healthcare. Examples include apps that measure heart rate and blood pressure, perform an ECG, manage the delivery of insulin, take patient-specific information and provide a clinician with radiation dosage calculations and allow doctors to view X-rays or other imaging on smart phones and tablets.

A device falls under the scope of the Medical Device Directive if it has a medical purpose as defined in the Directive. Areas for consideration include:

- Risks associated with design, manufacture and use should be managed as part of a comprehensive quality management system by, ideally, applying EN ISO 14971. Data integrity and security are concerns particularly when the data is transmitted wirelessly
- Usability compliance can most easily be demonstrated by meeting the requirements in the harmonised standard EN 62366 in the design process. If the device is for home use, studies should be carried out on samples of target users
- Software lifecycle processes become an important part of the design process. An applicable harmonised standard in this area is EN 62304
- Electromagnetic compatibility should be considered as an integral part of the development lifecycle. Wireless devices and products that are wired to the telecoms network, also fall under the scope of the R&TTE Directive so the EN 301 489 series of standards will most likely apply
- You should also ensure that the device complies with the safety and essential performance requirements contained in the EN 60601 family of standards.

Unless the regulatory framework and requirements are taken into account in the early stages of the design process, you could find yourself needing to invest significant additional time and resources to obtain regulatory approval. Come and talk to BSI early to discuss your regulatory and clinical strategy.

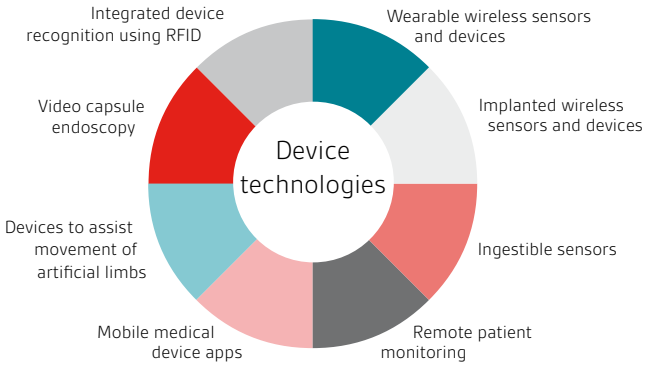
Why choose BSI for your certification?

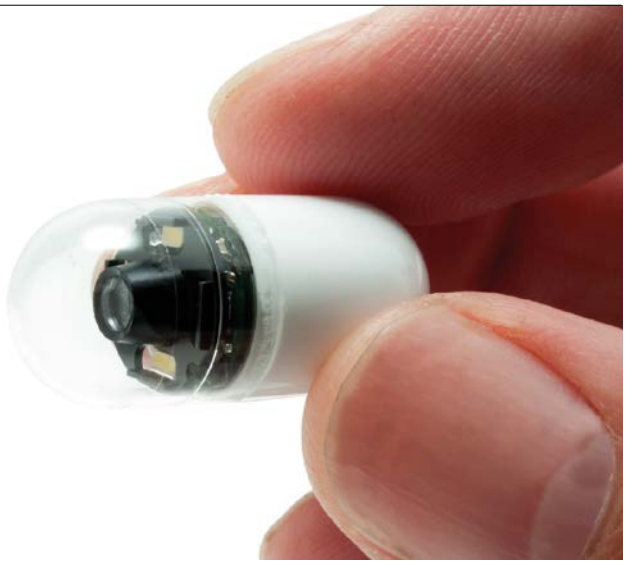
- Unrivalled expertise from the premier Mobile Devices Notified Body
- World-leading product specialists in the Active Devices & Active Implantable Medical Devices Teams with a wealth of experience gained from device and other regulated industries to understand the complete range of mobile devices
- Customized services to give you greater flexibility and accommodate your timelines
- Assessors and product specialists specifically trained to assess software lifecycle processes to EN 62304
- Ability to conduct assessments and provide certification against Annex V of the R&TTE Directive

bsi.

...making excellence a habit.™

BSI's mobile device experience includes:





Three unique reasons to make BSI your Notified Body

Experience and expertise – You can be rest assured by increased patient safety, thereby reducing your corporate risk.

Focus on service – BSI offer a premium customized service, giving you a greater level of flexibility as well as predictability.

Market Access – Our speed-to-market service means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more, please **call or email us for an initial conversation**

Your partner in worldwide compliance: Call BSI today on +44 345 080 9000 or visit bsigroup.com/medical-devices – to start your partnership

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