Software as a Medical Device

Unrivalled expertise from an EU Notified Body and UK Approved Body

As a manufacturer of software as a medical device, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market; for the EU, these are outlined in the Medical Device Regulation (MDR) (EU) 2017/745 and, for the UK, the UK Medical Devices Regulations (UK MDR) 2002.

It is critical to work with an EU notified body or UK approved body that understands the industry and has the experience to review and confirm your product's readiness for market – efficiently, reliably and promptly. Our technical specialists have extensive experience in certifying software as a medical device and can support you through the process of certifying your software.

BSI The Netherlands (2797) is a leading Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations. BSI UK (0086) is a UK Approved Body able to provide conformity assessments under the new UKCA scheme.

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Inspiring trust for a more resilient world.

Defining Software as a Medical Device (SaMD)

The effect of software on the safety and performance of medical devices has continued to grow in significance over recent years. The assessment of software has raised more questions than answers, but now there are clearer definitions and regulatory requirements that must be followed for any software that is classified as a medical device.

The steps you take to define, classify, develop, and test your software are critical to both your business and patient health.

Is my software a medical device?

The first stage is to confirm your product or service is legally classified as an SaMD; the product must first have a stated intended purpose that is medical as defined by the Medical Device Directives and Regulation in the EU and the UK Medical Devices Regulation (UK MDR) 2002.

The European Commission's guidance, MEDDEV 2.1/6, is only applicable to standalone software.

As indicated in the EU MDD/MDR and UK MDR, standalone software which has a medical purpose is considered to be an active medical device. Classification depends on the risk to the patient and users. To classify your software fully, you will need to review the relevant classification rules.

What about my App?

Mobile Apps must meet the same requirements outlined; the MHRA has listed words used to describe an App that is likely to be associated with a medical device:

- Amplify
- Interpret
- Calculates
- Analysis
- Alarms
- Controls

Does the software create, modify, or facilitate the interpretation or perception of medical information?

If so it might qualify as a medical device

Regulatory documents relating to SaMD

Mandatory Directives and Regulations		Harmonized/State-of-the-Art Standards		Guidance documents	
92/42/EEC (MDD)	2017/745 EU MDR	EN ISO 14971	EN 60601-1	MEDDEV 2.1/6	NB-MED/2.2/Rec4
90/385/EEC (AIMDD)	2017/746 EU IVDR	EN ISO 13485	EN 62366	IEC/TR 80002-1	MDCG 2019-11
90/79/EC (IVDD)	UK MDR 2002	EN 62304	EN ISO 12207		

Development of Medical Device Software

Before you start to develop your software, identify the relevant Directives and Regulations, standards, and guidance documents recommended to develop, maintain, and validate medical software according to the State of the Art. The diagram above contains the documents you should consider as a starting point. Early consideration of the regulatory requirements will reduce the need to rework your software later in the development cycle.

Consider who will use the software, and ensure the user interface is suitable for your target operator; different language and knowledge should be assumed based on the software being used by a patient directly or a clinician.

Software validation

The Directives and Regulations require employing "State-of-the-Art" methods of software validation, therefore you should stay up to date in the fast-paced and ever-changing software market.

Software developed by others

The internal software that you develop specifically for your device may need to comply with the medical device Directives and Regulations, but you also need to consider software developed by subcontractors and SOUP (Software of Unknown Provenance), including off-the-shelf software.

BSI's SaMD experience includes:

Infusion pump rate setting assistance software; Picture Archiving and Communication Software (PACS); image processing software; standalone application software for remotely collecting patient data for clinicians to analyze; standalone software used to program and collect data from implantable devices; Apps for phones (e.g. ECG, ophthalmic assessments and radiation therapy planning software).

Reasons to work with BSI Medical Devices

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of more than 750; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards

BSI is a global network of over:

5,000 people **supported by** 12,000 industry experts **in more than** 193 countries

Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. BSI The Netherlands (2797) is a leading Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations. BSI UK (0086) is a UK Approved Body able to provide conformity assessments under the new UKCA scheme.

Confidence and robust reviews

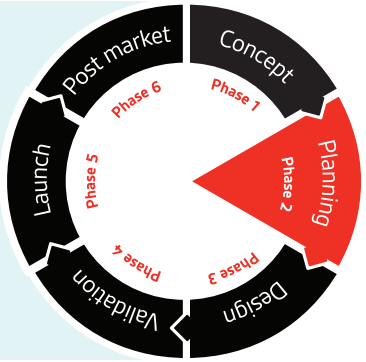
Our comprehensive review process combined with our world-leading medical device and regulatory experience will ensure that your conformity assessment process is both efficient and robust.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

The Product Lifecycle: when to consider clinical and regulatory requirements

An understanding of the complex clinical and regulatory requirements early in the product lifecycle could ensure you gain the competitive advantage needed to bring your product to market. Consolidated clinical and regulatory planning will assist you in maximizing resources and reducing the risk of costly redevelopments later in the lifecycle.
Visit our website for more information about the product lifecycle.



How can BSI support your software medical device launch?

Be prepared

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized Certification Body in Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Navigating your transition to the IVDR and MDR

The Medical Devices Regulation (MDR) (EU) 2017/745 has a transition period of four years starting from May 2017, after which the Regulation will apply. The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 entered into force on the 25 May 2017 marking the start of a five-year transition period.

Manufacturers have the duration of the transition periods to update their Technical Documentation and processes to meet the new requirements if they want to place medical devices and in vitro diagnostic medical devices on the market in the European Union.

The MDR brings with it more scrutiny of Technical Documentation, addressing concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up. The IVDR brings with it significant changes to the regulatory requirements for IVD medical device manufacturers and introduces a new rule-based classification system with stricter notified body oversight, as well as significant changes to the depth and requirements of the associated Technical Documentation.

Visit our website for more information: bsigroup.com/medical

Technical Documentation Review

Our Technical Documentation Review services deliver the efficiency you need to be both competitive in the market and maintain confidence through our robust technical reviews.

Standard

Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.

Dedicated

This service allows you to schedule your Technical Documentation review with a dedicated BSI Product Expert.

Five steps to CE or UKCA marking your product

Step 1

BSI prepares a quotation

A BSI representative meets with your organization to discuss your needs and the available solutions. We will also discuss the best service for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification decision

Successful assessment leads to your BSI scheme manager recommending certification of your product. The BSI Certificate Decision Maker will then review the recommendation and, if satisfactory, approve certification.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE or UKCA mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

Talk to BSI today

Call: **+39 02 66 79 091**

Visit: **bsigroup.com/it-IT/Dispositivi-Medici**

and start your journey

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