Expertise and experience

Helping you understand Software as a Medical Device

Updated May 2017

bsi.

...making excellence a habit.™

The effect of software on the safety and performance of medical devices has continued to grow in significance over recent years. This is particularly relevant when the device itself is a software only product. 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 long established three Medical Device Directives (Medical Device Directive (MDD), Active Implantable Medical Device Directive (AIMDD) and In Vitro Diagnostic Directive (IVDD)), effectively encompass software embedded within a conventional medical device, this would then be classified as part of the product and not require separate consideration.

This document provides information regarding Standalone Software as a Medical Device (SaMD). The steps you take to define, classify, develop, and test your software is critical to both your business and patient health when it applies to a medical device. Meeting the requirements of the applicable Medical Directive and applying CE marking has to take place before the medical device software can be placed on the market within Europe.

The Medical Device Directives state:

'For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.'

Is my Software a Medical Device?

The first stage is to confirm your product or service is legally classified a SaMD; the product must first have a stated intended purpose that is medical as defined by the Medical Directives. It is sometimes difficult to determine if your software or part (modules) of the software has a medical purpose; for borderline products, you should consult MEDDEV 2.1/6. If software is an accessory to a medical device, MEDDEV 2.1/6 states, "if the software is an accessory to a medical device, it is not a medical device, but it falls under the MDD 93/42/EEC."

If you are unsure regarding classification, please come and talk with BSI.

The European Commission's guidance MEDDEV 2.1/6 is only applicable to standalone software which it defines as:

"Software which is not incorporated in a medical device at the time of its placing on the market or its making available."

As indicated in the MDD, 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 rules 9, 10, 11 and 12 of Annex IX of the MDD and also Annex IX, 2.3: Software which drives a device or influences the use of a device, falls automatically in the same device class.

AIMD and IVD Directives

Standalone software shall be classed as an AIMD/ IVD or an accessory to an AIMD/ IVD provided that it meets the definition contained in the relevant Directive.

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
- Analysis
- Interpret
- Alarms
- Calculates
- Controls
- Converts
- Detects
- Diagnose
- Measures
- Monitors

You should also think about the following questions:

Does the software;

- Create medical information
- Modify medical information
- Facilitate perception of medical information
- Facilitate interpretation of medical information

If so it might qualify as a medical device.

Development of Medical Device Software

Before you start to develop your software, identify the relevant directives, standards, and guidance documents recommended to develop, maintain, and validate medical software according to the State of the Art. The diagram below 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.

It is critical you are prepared early in the development process to develop the basic knowledge necessary to evaluate software lifecycle processes and risk management to ensure that they are compliant with the medical directives.

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.

Regulatory Documents relating to SaMD

Mandatory Directives	Harmonized standards	Non-harmonized standards	Guidance documents
92/42/EEC (MDD) 90/385/EEC (AIMDD) 90/79/EC (IVDD)	EN ISO 14971 EN ISO 13485 EN 62304 EN 60601-1 EN 62366	EN ISO 12207	MEDDEV 2.1/6 IEC/TR 80002-1 NB-MED/2.2/Rec4

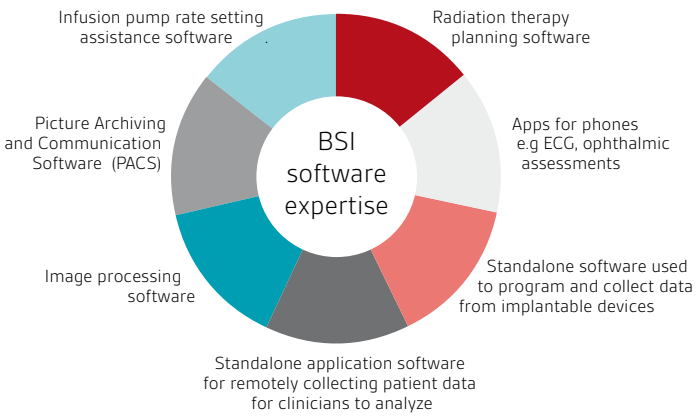
Software Validation

The Directives 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, 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:



Why choose BSI for certification?

Many BSI QMS assessors and client managers are medical device life cycle experts.

Many of our active medical device and IVD instrument assessors and client managers have significant years of experience auditing medical device software for compliance with IEC 62304.

BSI Software Technical Specialists are software life cycle process experts having performed technical visits to client sites and design dossier reviews, assessing any medical devices with software for compliance with the medical device directives for CE marking purposes.

Several of BSI's QMS assessors have TickIT certification (third-party certified through IRCA) and conduct process-based audits taking into account ISO/IEC 90003:2004, Software and System Engineering Guidelines for the application of ISO 9001 to computer software.

Three unique reasons to make BSI your Notified Body

Experience and expertise

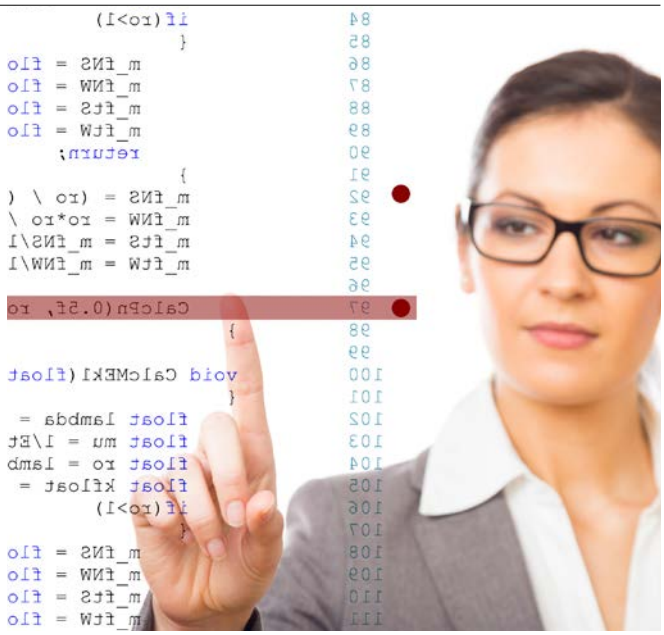
– BSI focuses on excellence, thereby reducing your corporate risk.

Focus on service

– BSI offers a range of review services, giving you a greater level of flexibility as well as predictability.

Market Access

– Our efficient review services means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.



Talk to BSI

Come and talk to BSI early regarding the regulatory framework and requirements to ensure all factors are taken into account in the early stages of the design process.

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

The trademarks in this material (for example the BSI logo or the word "KITEMARK") are registered and unregistered trademarks owned by The British Standards Institution in United Kingdom and certain other countries throughout the world.

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800,
Herndon,
VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac
BSI Group - Hong Kong
23rd Floor, Cambridge House
TaiKoo Place,
979 King's Road,
Island East, Hong Kong

T: +852 3149 3320
F: +852 2743 8727
E: hk@bsigroup.com

Visit us online at: bsigroup.com/medical

BSI/UK/008/MD/0417/en/BLD

© BSI Group