Your partner
in progress

Software as a Medical Device

EU Notified Body, UK Approved Body and Auditing Organization Expertise

As a manufacturer of a SaMD, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market.

Europe: Medical Device Regulation (MDR)(EU) 2017/745

Great Britain: Medical Devices Regulations (UK MDR 2002)

Global Medical Device Single Audit Program (MDSAP)

It is critical to work with a trusted EU Notified Body or UK Approved Body or Auditing Organization that understands the industry and has the experience to review and confirm your product's readiness for market - efficiently, promptly and robustly.

Our Technical Specialists have extensive experience in SaMD medical devices and can support you through the process of certifying your device.

BSI The Netherlands (2797) is a leading full-scope 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 full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

BSI Group America Inc. is a recognized Auditing Organization.

Defining Software as a Medical Device (SaMD)

It should be noted that the terms "Software as a Medical Device" (SaMD) and "Software in a Medical Device" (SiMD) are terms defined in FDA and IMDRF guidances. These terms do not appear in the EU Medical Device Regulation. In Vitro Diagnostics Regulation, or associated MDCG Guidance documents. The EU guidance document MDCG 2019-11 instead defines the term "Medical Device Software" (MDSW) and this definition encompasses all types of software with a medical purpose or acting as an accessory to a medical device, including software embedded within a dedicated hardware medical device.

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 and follow the relevant guidance.

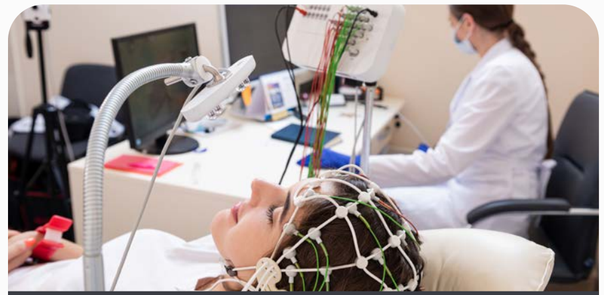
For the purposes of this brochure, the term "SaMD" is used to signify the following subset of MDSW:

- MDSW having its own independent medical intended purpose (i.e. it is not dependent on a specific hardware medical device).
- MDSW intended to be installed on a general computing platform (e.g. smartphone, tablet, PC, cloud deployment, etc.) as opposed to installation on a purpose-built medical hardware platform.

Product range covered

ECG interpretation software

Behaviour modification software



Sleep and epilepsy software

Dental implant planning software

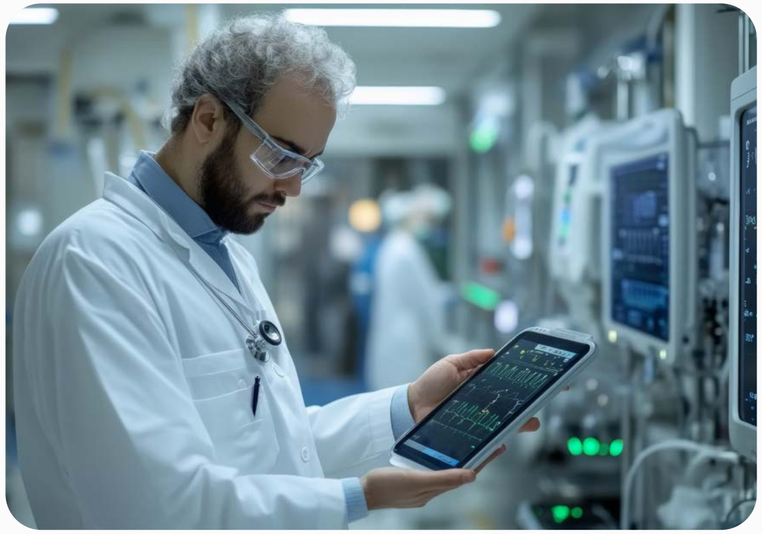
Image interpretation software

Health monitoring software

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.

Guidance on Qualification and Classification of Software in Regulation **(EU) 2017/745 – MDR** and Regulation **(EU) 2017/746 – IVDR**, **MDCG 2019-11.**



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
- Analysis
- Interpret
- Alarm
- Calculate
- Control

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

93/42/EEC (MDD)
90/385/EEC (AIMDD)
90/79/EC (IVDD)
(EU) 2017/745 (MDR)
(EU) 2017/746 (IVDR)
(EU) 2021-2226 (eIFU)
(EU) 2016/679
UK MDR 2002

Harmonized/State-of-the-Art Standards

EN ISO 14971
EN ISO 13485
EN 62304
EN 82304-1
IEC 81001-5-1
EN 62366-1
EN ISO 12207
IEC/TR 80002-1

Guidance documents

MDCG 2019-11
MDCG 2019-16
MDCG 2020-1
MDCG 2018-5
MHRA guidance SaMD and AIaMD
NBOG 2014-3

Development of Medical Device Software

Please consult the section "Regulatory documents relating to SaMD" on the previous page for a list of relevant documents you should consider as a starting point.

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. Clinical performance and usability should be considered as part of how the SaMD will ultimately meet its intended user needs.

Software developed by others

All software included in the medical device software (MDSW) must comply with the medical device Directives and Regulations. The legal manufacturer bears responsibility for the software, even if the software is developed by subcontractors, or contains SOUP (Software of Unknown Provence) or “off-the-shelf-software”.

BSI’s SaMD experience includes:

- Cognitive behavioral therapy software
- Computer-aided diagnosis software
- Continuous glucose monitoring software for diabetes
- ECG analysis software
- Fertility planning software
- Pulmonary function testing software
- Remote patient monitoring software
- Sleep diagnostics software
- Epilepsy warning software
- Ophthalmic assessments software
- Radiation therapy planning software
- Mobile applications and much more

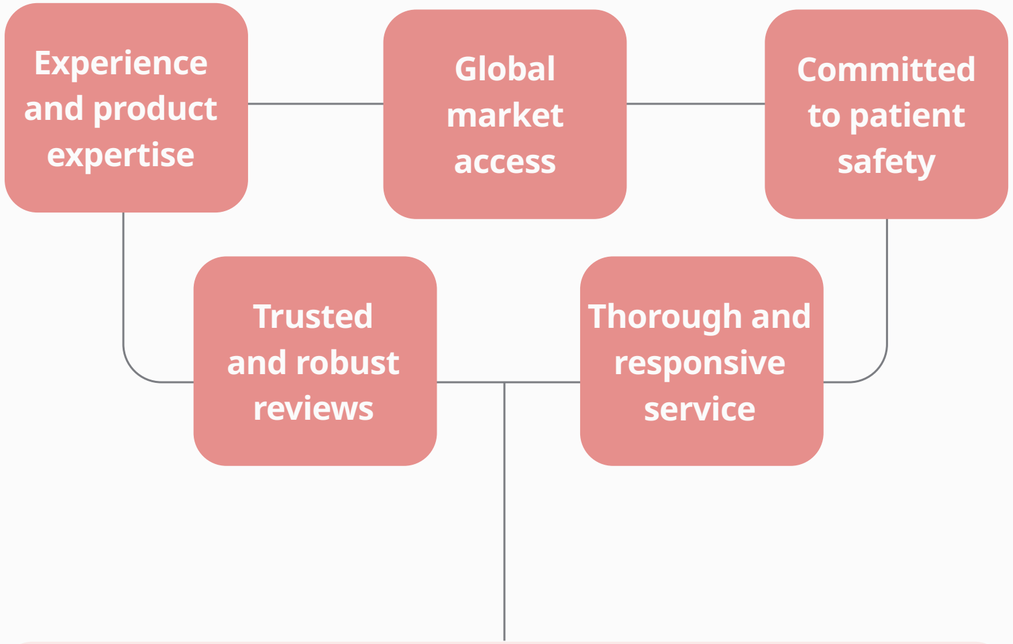
Meet our SaMD Team

Our dedicated SaMD team brings extensive expertise in artificial intelligence, software development, and cybersecurity. The team is well-versed in the challenges of CE marking of software, ensuring the compliance, safety, and performance of SaMDs through efficient conformity assessments aligned with applicable regulations.

> “ Transparency and predictability in certification activities for Software as a Medical Device are crucial for manufacturers of this rapidly evolving technology. Frequent and efficient updates to approved devices must occur without compromising compliance with medical device regulations. With our dedicated software team, we focus on this essential medical device segment, helping to deliver innovative solutions to patients.

Thomas Doerge
Global Head of AIMD and SaMD, BSI

Why choose BSI



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

Experience and product expertise

In the complex and ever-changing medical device industry, support from experienced, professional and well qualified technical specialists is critical.

BSI Medical Devices consists of a team of over 1000 professionals including technical experts and internal clinicians with expertise encompassing the full range of medical devices and management system standards.

Committed to 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 and robust conformity assessments, evaluations and certifications.

Thorough and responsive service

We truly understand the challenges medical devices manufacturers face in bringing compliant products to market efficiently and safely.

We offer standard and dedicated review services providing you with the efficient pathways to bring your device 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 toprovide conformity assessments under the UKCA scheme.

BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP).

BSI is a Conformity Assessment Body for EN ISO 17021-1 (EN-ISO 9001, ISO 14001, ISO 13485) as accredited by the Dutch Accreditation Council (RvA) and the UK Accreditation Service (UKAS).

Trusted and robust reviews

Our comprehensive review process combined with our world-leading experience as a Notified Body and UK Approved Body will ensure that your conformity assessment path is efficient and robust.

Five steps from product-to-market

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.

1

2

Conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your company throughout the process.

A QMS Audit will then be performed and all Technical Documentation reviewed by one of our experienced technical specialists.

Certificate decision

Successful assessment leads to your BSI scheme manager recommending certification of your product.

The BSI Certification Decision Team will then review the recommendation and, if satisfactory, approve certification.

3

4

Issue certificate

Upon successful certification, you will be issued with a certificate.

You will then be able to CE/UKCA mark your product and launch to market.

Certificate maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance.

Your BSI scheme manager will support you with any queries you might have.

5

How BSI supports your market readiness

Readiness

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

Worldwide Access

We offer a wide range of regulatory and quality management programs that work cohesively for international compliance. BSI is an accredited Conformity Assessment Body for Quality Management Systems against ISO 17021-1with ISO 13485, ISO 9001 and ISO 14001 in its scope.

BSI Group The Netherlands B.V. (2797) is a leading Notified Body achieving full-scope designation under MDR and IVDR.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI Group The Netherlands B.V. (2797) is a recognized “Notified Body partner” in Taiwan’s Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

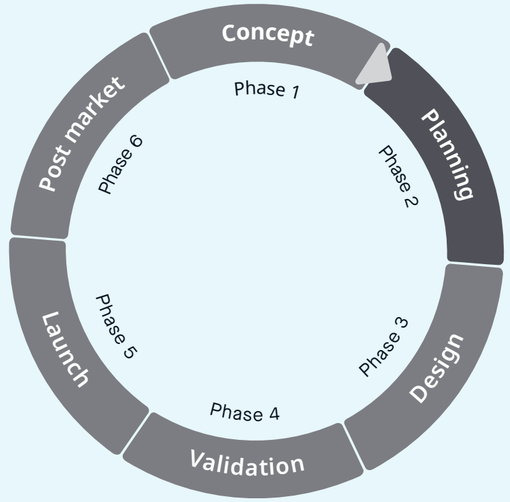
BSI Transfer

We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

Additional Services

- **Access to more than 34,000 standards** and related products, as well as online guidance documents
- **Expert training** online or face-to-face through our public training courses and read our **Excellence Pathways brochure**
- **Regulatory updates and newsletters** focusing on industry changes, helping you to plan for the future
- **Webinars** delivered by our experts on regulatory issues
- **Comprehensive whitepapers** providing the latest insights on key industry topics

The product lifecycle



Considering 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.

Our consolidated clinical and regulatory planning will support 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

Navigating your compliance to the MDR

The MDR (EU 2017/745), which replaced the AIMDD (90/385/EEC) and MDD (93/42/EEC), applied on May 2021. Manufacturers must ensure their Technical Documentation and processes meet the new requirements for placing medical devices on the EU market.

Manufacturers are invited to apply to a Notified Body for MDR to ensure compliance with the Regulation.

Starting the certification process?

Transitioning to MDR?

Transferring your existing certification?

From the experts

Strong, statistically relevant clinical data demonstrating the safety and performance of your device is essential to ensuring a successful outcome of your MDR application.

MDR Best Practices Guidelines to support you

Conformity Assessment guidance to meet MDR requirements

Continued access to our technical experts throughout your submission

CE/UKCA Excellence

Technical Documentation Review Services deliver the efficiency you need to be competitive in the market and maintain trust.

Standard

Access to technical review timeline after Technical Documentation submission.

Dedicated

Technical review planned up-front to Technical Documentation submission.

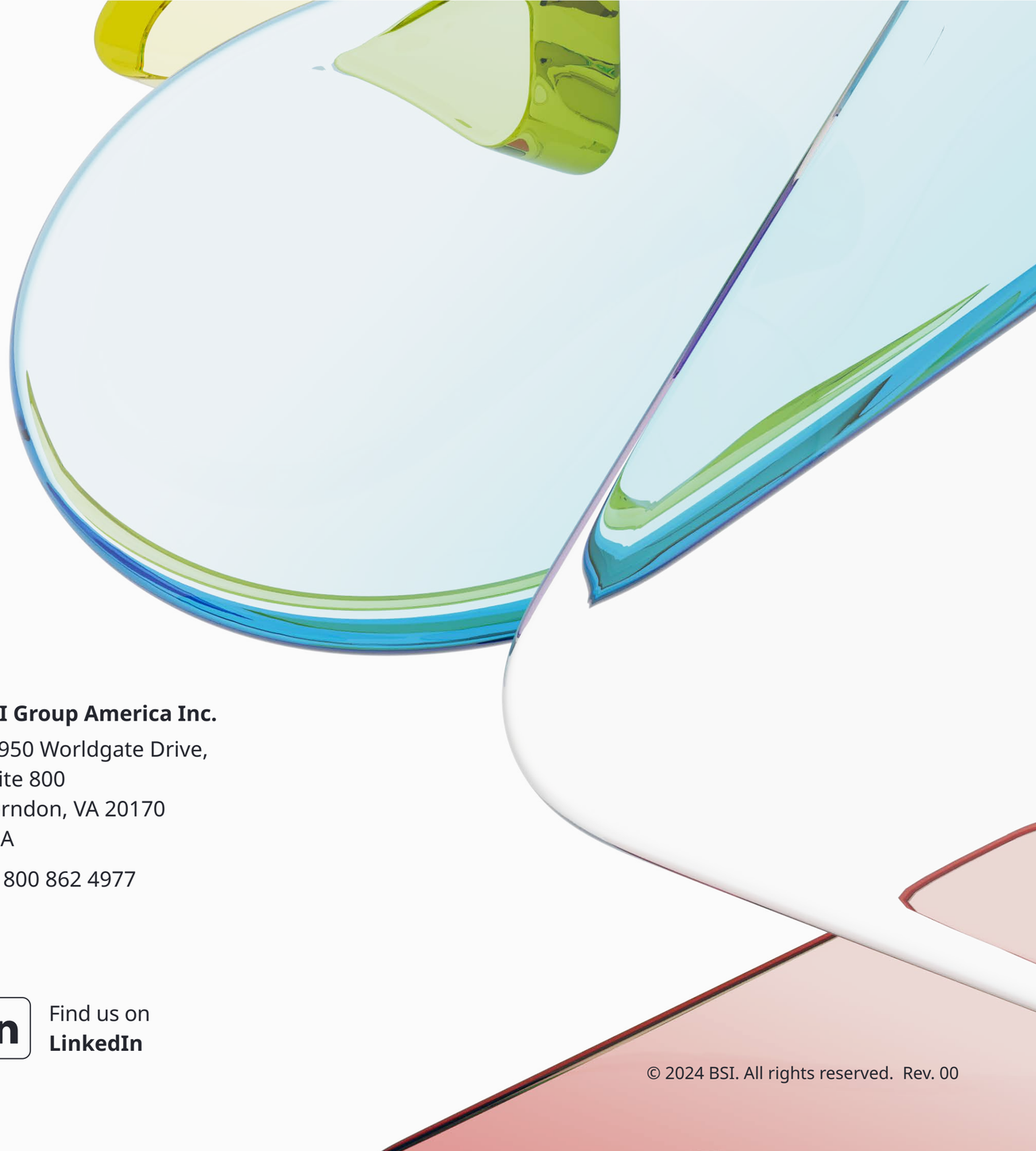
Talk to BSI today and start your journey

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

Your partner
in progress



BSI Assurance UK Ltd (0086)
Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

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

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn