Medical Device Software under the MDR

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27 March 2025

Agenda

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02 Key GSPRs

03 Key Standards

04 Key Guidance

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Disclaimer

What is presented today is based on our current knowledge and interpretation of the MDR and the latest available MDCG guidance.

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SaMD / SiMD

IMDRF –MDR - Definitions

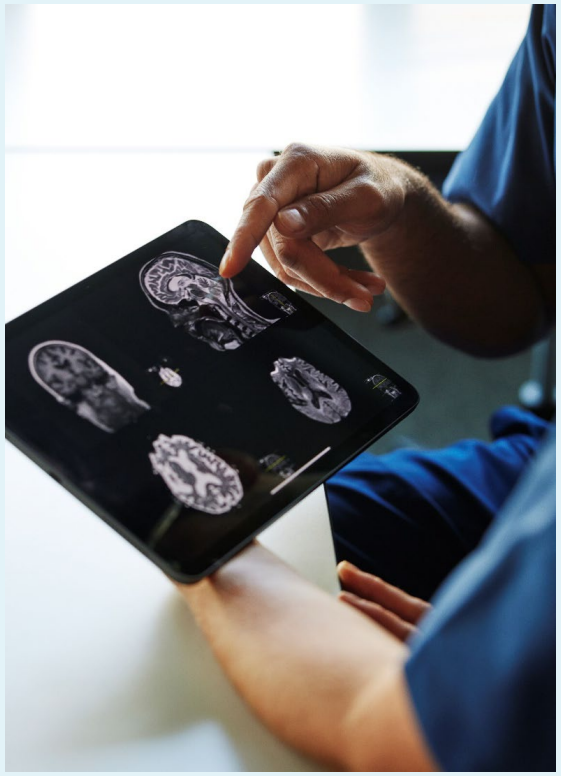
It should be noted that the terms “Software as a Medical Device” (SaMD) and “Software in a Medical Device” (SiMD) are terms defined in FDA and IMDRF guidances.

These term “SaMD” does 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 defintion 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.

For the purposes of this presentation, the term “SaMD” is used to signify the following subset of MDSW:

MDSW with 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



Software as Medical device (SaMD)

Introduction

Medical device software

Regulation (EU) 2017/745 – MDR

Article 2 - Definitions

(1) '**medical device**' means any instrument, apparatus, appliance, **software**, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for **one or more of the following specific medical purposes**:

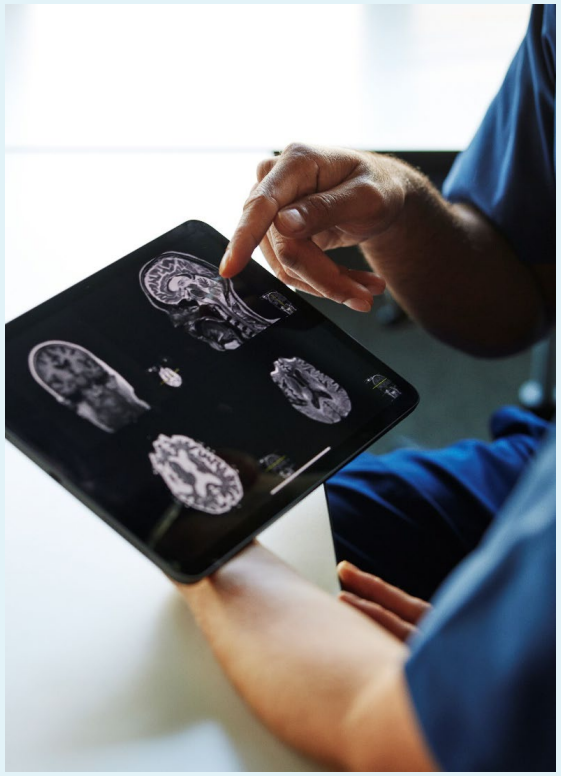
— **diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation** of **disease**,

— **diagnosis, monitoring, treatment, alleviation of, or compensation** for, an **injury or disability**,

— **investigation, replacement or modification** of the **anatomy** or of a **physiological or pathological process or state,**

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.....

(4) '**active device**' means any device..... **Software shall also be deemed to be an active device....**



Medical device software

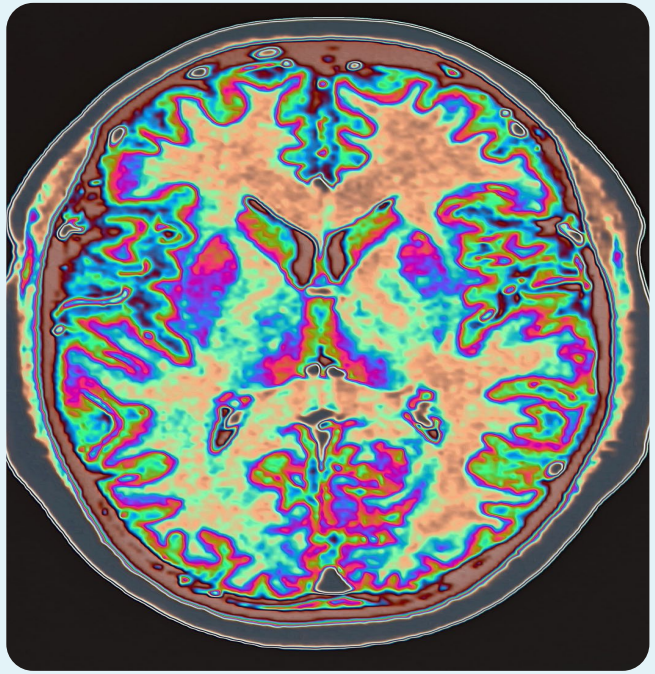
MDCG 2019-11 - Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR….

Software

For the purpose of this guidance, “**software**” is defined as a set of **instructions that processes input data and creates output data.**

Medical Device Software (MDSW)

Medical device software is software that is intended **to be used, alone or in combination, for a purpose as specified in the definition of a “medical device”** in the medical devices regulation or in vitro diagnostic medical devices regulation.



Medical device software

Intended purpose and indication for use

MDR – Article 2 (12)

(12) '**intended purpose**' means the use for which a device is **intended according to the data supplied** by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

MDCG 2020-6

'indication', '**indication for use**': refers to the **clinical condition** that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device. It should be distinguished from 'intended purpose/intended use', which describes the effect of a device…..

Medical device software

MDR – Annex VIII Chapter III – Classification rules – Rule 11

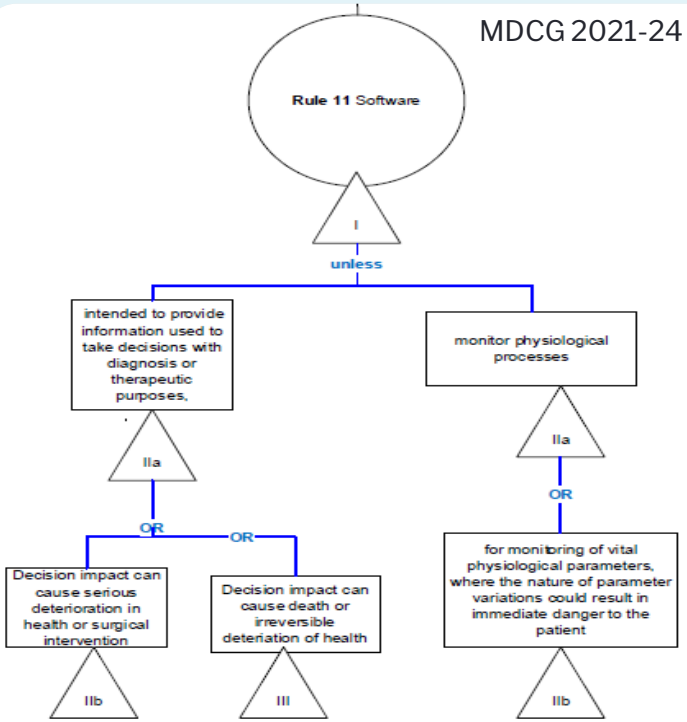
Software intended to **provide information** which is used to **take decisions with diagnosis or therapeutic purposes** is classified as **class IIa**, except if such decisions have an impact that may cause:

— **death or an irreversible deterioration** of a person's state of health, in which case it is in **class III**; or
— **a serious deterioration** of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.

Software intended to monitor physiological processes is classified as **class IIa**, except if it is intended for monitoring of vital physiological parameters, where the **nature of variations** of those parameters is such that it could **result in immediate danger** to the patient, in which case it is classified as **class IIb**.

All other software is classified as class I.

MDCG 2021-24



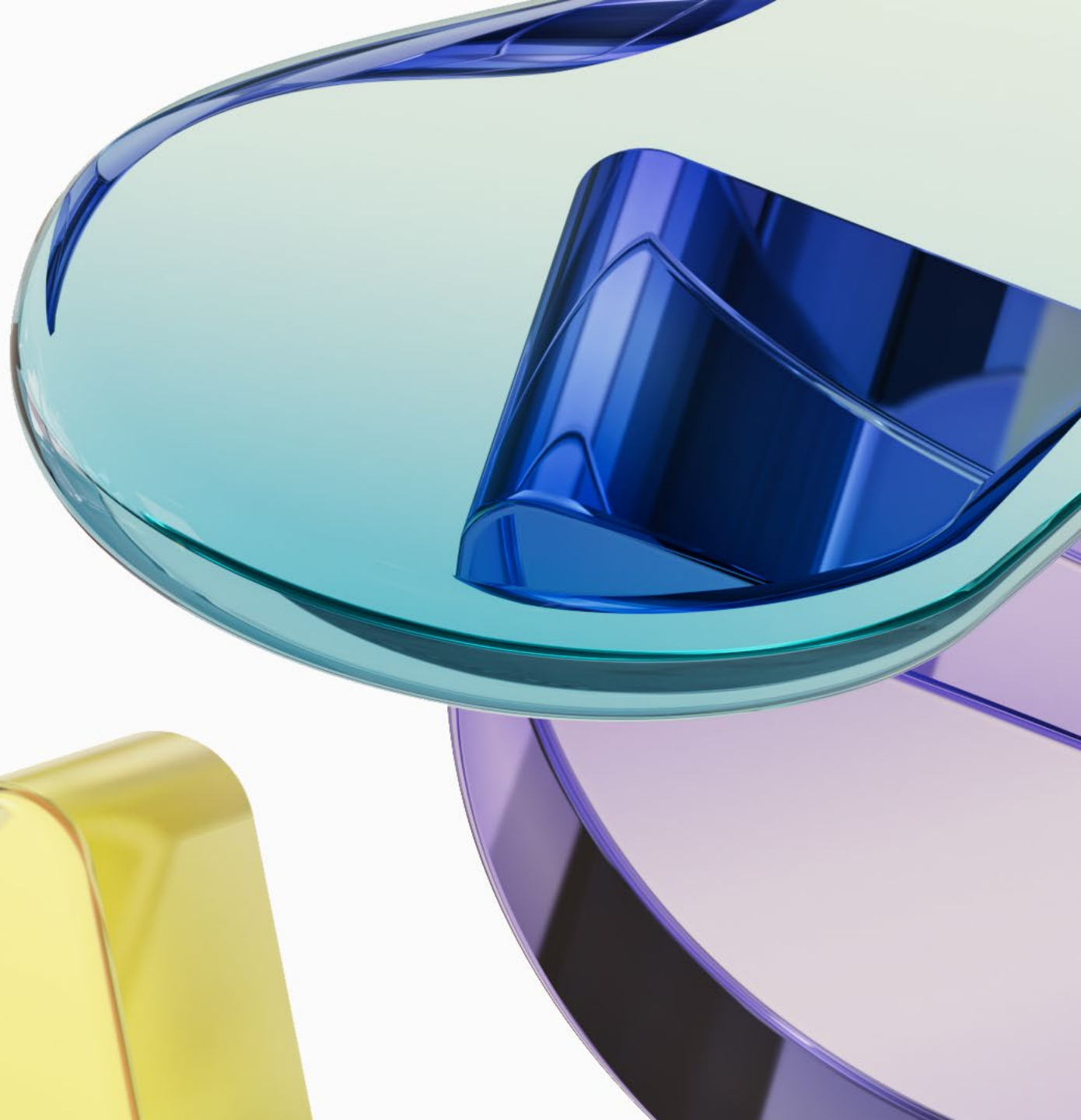
Medical device software

MDCG 2021-24 - Guidance on classification of medical devices.

- Provides additional clarifications and examples of device classification under EU MDR (I, IIa, IIb, III)
- Example of class I software provided

Class	Rule 11	Examples
IIa	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:	• MDSW intended to rank therapeutic suggestions for a health care professional based on patient history, imaging test results, and patient characteristics, for example, MDSW that lists and ranks all available chemotherapy options for BRCA-positive individuals. • Cognitive therapy MDSW where a specialist determines the necessary cognitive therapy based on the outcome provided by the MDSW.
III	— death or an irreversible deterioration of a person's state of health[1], in which case it is in class III; or	• MDSW intended to perform diagnosis by means of image analysis for making treatment decisions in patients with acute stroke.
IIb	— a serious deterioration of a person's state of health[1] or a surgical intervention, in which case it is classified as class IIb.	• A mobile app intended to analyse a user's heartbeat, detect abnormalities and inform a physician accordingly. MDSW intended for diagnosing depression based on a score resulting from inputted data on patient symptoms (e.g. anxiety, sleep patterns, stress etc.).
IIa	Software intended to monitor physiological processes is classified as class IIa,	• MDSW intended to monitor physiological processes that are not considered to be vital. • Devices intended to be used to obtain readings of vital physiological signals in routine check-ups including monitoring at home.
IIb	except if it is intended for monitoring of vital physiological parameters[3], where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.	• Medical devices including MDSW intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care.
I	All other software is classified as class I.	• MDSW app intended to support conception by calculating the user's fertility status based on a validated statistical algorithm. The user inputs health data including basal body temperature

Key GSPRs



Key GSPRs

MDR GSPR 14 - Construction of devices and interaction with their environment

- **GSPR 14.1** - If the **device is intended for use in combination with other devices or equipment the whole combination,** including the connection system **shall be safe** and shall not impair the specified performance of the devices……

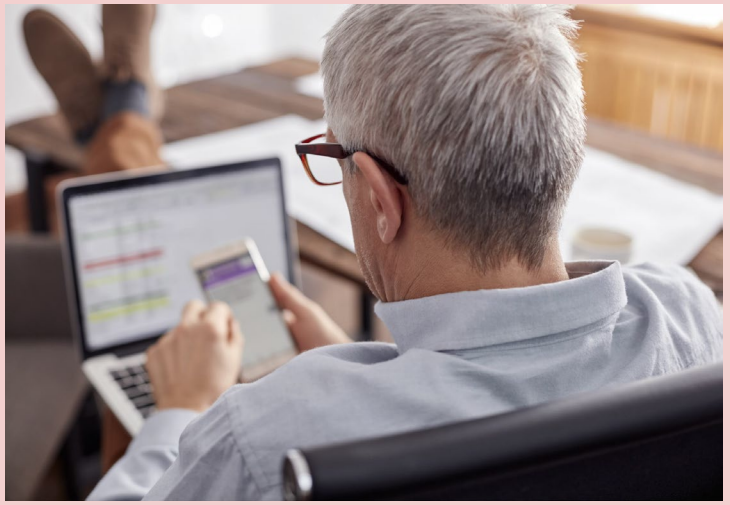
  Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to **minimise all possible risks**, such as misconnection.

- **GSPR 14.5** - **Devices that are intended to be operated together with other devices** or products shall be designed and manufactured in such a way that the **interoperability and compatibility are reliable and safe.**

Key GSPRs

MDR GSPR 14 - The Notified Body will want to know:

- Are the **intended platforms** for the SaMD **clearly defined**?
- Are the **intended operating systems** on which the SaMD executes **clearly specified**?
- Have designated **compatible SaMD/platform/OS combinations been tested** to ensure interoperability to achieve expected levels of safety and performance?
- Are **compatible platforms / restrictions** on platforms specified in labelling?



- How are **SW/OS updates controlled**/managed?
- How are **security updates/patches** deployed?
- Are safety related **security risks fully considered** and controlled? E.g.: Mitigations against threats ? Mitigations against threats to integrity of data/telemetry?
- Are **risks to confidentiality** considered and controlled? E.g.: Encryption of data at rest? Encryption of data in transit?

Key GSPRs

MDR GSPR 17 - Electronic programmable systems

Devices that incorporate electronic programmable systems & software that are devices in themselves

- **GSPR 17.1** - Devices that incorporate electronic programmable systems, including software, or **software that are devices in themselves**, shall be designed to ensure **repeatability, reliability and performance** in line with their intended use. **In the event of a single fault condition**, appropriate means shall be adopted to **eliminate or reduce as far as possible consequent risks or impairment of performance.**

GSPR 17.2 - For devices that incorporate software or **for software that are devices in themselves**, the software shall be developed and manufactured in accordance with the ***state of the art** taking into account the **principles of development life cycle, risk management, including information security, verification and validation.**

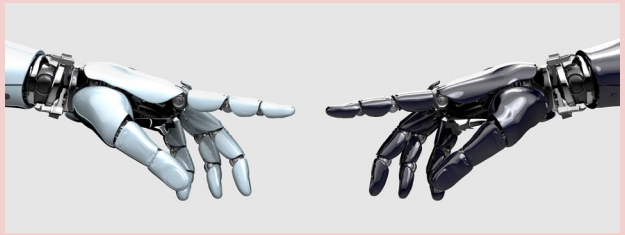
Key GSPRs

MDR GSPR 17 - The Notified Body will want to know:

- Is the **intended purpose** of the SaMD **clearly defined** (e.g. diagnostic function to detect some disease state)?
- If used for a **diagnostic function, are performance requirements** clearly established in requirements and **validated through testing**? (e.g. Sensitivity and Specificity)
- Are **applicable requirements** categories clearly defined and **demonstrated via testing**? (see EN 62304 Clause 5.2.2)

- Has **cybersecurity been addressed** consisted with the state-of-the-art (SOTA)? **MDCG 2019-16 – SOTA** for cybersecurity for medical devices

- Are **development, testing, and risk management methods used representative of the state-of-the-art (SOTA)**?



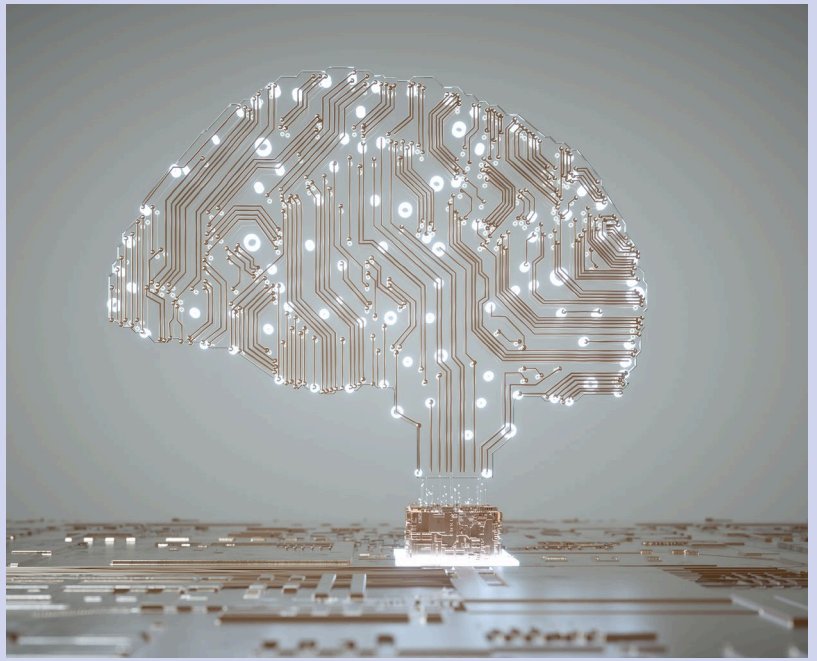
Key Standards

Key Standards

EN 62304:2006+A1:2015

Medical device software – Software life-cycle processes

- Current SOTA for all MDSW, areas covered:
- General requirements for software
- Software safety classification [A, B, C], drives required activities defined in the standard
- Software development PROCESS
- Software maintenance PROCESS
- Software RISK MANAGEMENT PROCESS
- Software configuration management PROCESS



Key Standards

EN 62304:2006+A1:2015

The Notified Body will want to know, key points:

- Is an EN 62304 Compliance Matrix provided?
- Is SW Safety Classification, correct?
- Are all required artefacts of the SW development process provided (as per SW safety class)? Such as; SW Development Plan, SW Requirements, SW Architecture, SW Detailed Design, Unit Implementation & Unit Verification, SW Integration & SW Integration Testing, SW System Testing, SW Release documentation etc.
- SW risk assessment provided (or included in system risk documents)?
- All known anomalies documented [A, B, C]? Each anomaly assessed for risk and justified [B, C]?

EN 82304-1:2017

Health Software Part 1: General requirements for product safety

HEALTH SOFTWARE

Software intended to be used specifically for managing, maintaining, or improving health of individual persons, or the delivery of care

Areas covered:

- **Health software product requirements**
- **Health software – Software life cycle processes**
- **Health software product validation**
- **Health software product identification and accompanying documents**
- **Post-market activities for the health software product**

EN 82304-1:2017

Health Software Part 1: General requirements for product safety

The Notified Body will want to know:

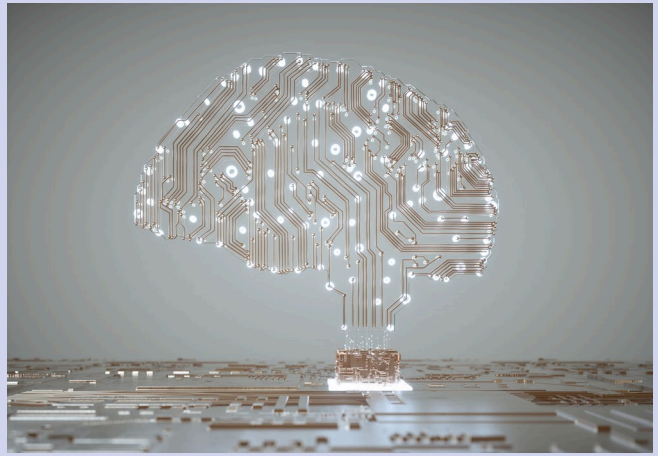
- Has EN 82304-1 been applied for SaMD? ➔ Is an EN 82304-1 Compliance Matrix provided?
- Is there a documented intended use including user profile and operational environment?
- SW product requirements established? E.g. characteristics related to safety and security; risk control measures; configuration; interfaces to other products
- System requirements established? E.g. functionality, localization, user interface, SW and HW platforms, detection of security compromise, protection of essential functions
- Verification of system requirements performed and documented?
- SW lifecycle process aligned with EN 62304?
- Has Software Product Validation been conducted? Is it appropriate (see next slide)

EN 62366-1:2015+A1:2020

Medical devices Part 1: Application of usability engineering to medical devices

Areas covered:

- **Principles (General requirements, usability engineering file, etc.)**
- **Usability Engineering Process**
  - Use specification
  - UI characteristics related to safety/potential use errors
  - Hazard-related use scenarios for summative evaluation
  - User interface specification
  - Planning for formative, summative evaluations
  - UI design, implementation, formative evaluation
  - Summative evaluation
  - User Interface of Unknown Provenance (UIOP)



USABILITY

Characteristic of the USER INTERFACE that facilitates use and thereby establishes EFFECTIVENESS, EFFICIENCY and USER satisfaction in the intended USE ENVIRONMENT

EN 62366-1:2015+A1:2020

The Notified Body will want to know:

- Has EN 62366-1 been applied for SaMD?
  ➔ Usability process constitutes part of the design validation
- Has usability been addressed in the risk management file?
- Have formative and/or summative testing been conducted?
- If either formative and/or summative testing has not been conducted, has a valid rationale been provided? (e.g. based on risk, PMS data, etc.)
- Was testing conducted with representative users? (e.g. clinicians, lay users, etc. as per defines USER PROFILE)
- Are sample sizes/number of users tested appropriate?
- Are usability issues encountered during the usability engineering process tracked/dispositioned/implemented into the UI design appropriately?

Key Guidance

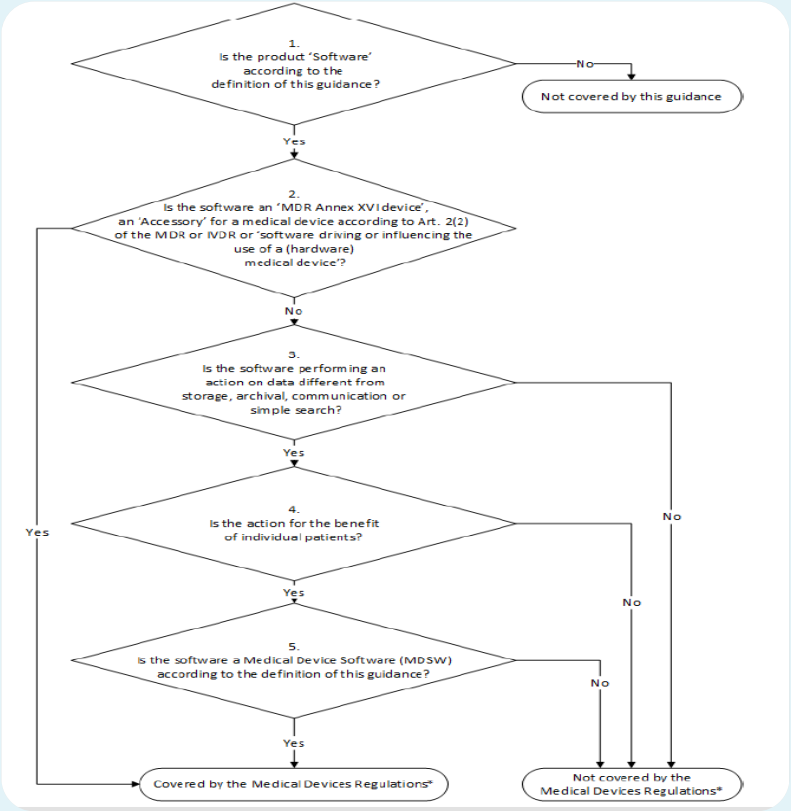
Software as medical device

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

- Scope is to understand if a particular software is considered **“Medical Device Software”** and thus regulated under MDR and/or IVDR
- **Decisions steps for classification** of MDSW under MDR

- Considerations for **placing MDSW on the market** and conformity assessment:
  - ❖ **As a medical device in its own right**
  - ❖ **As an integral component/part of a device**

- Examples (MDSW and non-MDSW)
- Application of IMDRF risk classification for **MDR Rule 11**



IMDRF risk classification framework in the context of the MDR

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

State of Healthcare situation or patient condition	Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
	High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

Table 1: Classification Guidance on Rule 11

This table does not take into account MDSW which is Class I.

The table 1, which is intended for illustrative purposes only, may provide operators placing MDSW on the EU market with some useful indicative orientation on the risk class applicable to their products as a result of the application of Rule 11 a of the MDR.

Key Guidance

MDCG 2020-1 - Guidance on Clinical Evaluation (MDR) ..... of Medical Device Software

- The following models of software are possible:
- a) Software for which the manufacturer **claims a specific medical intended purpose**. Such software has a CLINICAL BENEFIT and requires CLINICAL EVIDENCE within its own conformity assessment.
- b) Software for which the manufacturer **does not claim any medical intended purpose**. Such software is intended to drive or influence a medical device. The CLINICAL EVIDENCE is provided within the context of the driven or influenced device (...and is therefore out of the scope of this document.)

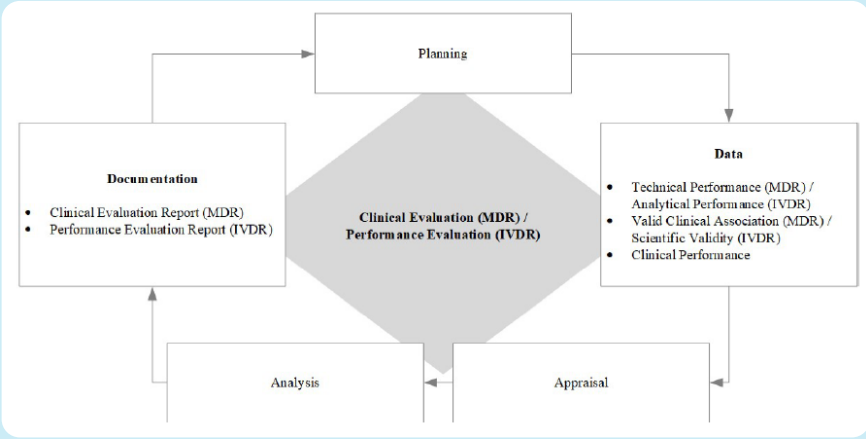
Model of Software	**CLINICAL EVALUATION** (MDR) / **PERFORMANCE EVALUATION** (IVDR) - **scope**
MDSW (with independent intended purpose and claimed CLINICAL BENEFIT)	MDSW only
MDSW (with intended purpose and claimed CLINICAL BENEFIT related to driving or influencing a medical device for a medical purpose)	MDSW and the driven or influenced medical device [Notes 1,2]
Software driving or influencing the use of a medical device (with no independent intended purpose or independent claimed CLINICAL BENEFIT)	Driven or influenced medical device including the software (component or accessory)

Evidence may be comprised of 3 items depending on the level of influence.

Key Guidance

MDCG 2020-1 - Guidance on Clinical Evaluation (MDR) …… of Medical Device Software

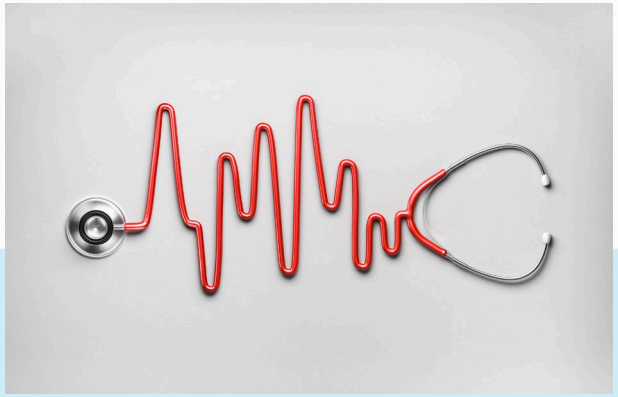
- **General principles** of MDSW clinical / performance evaluation process
- Determination of the **clinical association** / scientific validity
- Is **state-of-the-art appropriately considered** and documented in the CER?
- **Technical Performance / Analytical Performance/ Clinical Performance**



- Clinical investigations and clinical performance studies conducted to **support the claims** made for the MDSW?
- Where equivalence is claimed, **is the equivalence analysis appropriate**?
- Are the **pre-clinical performance testing and validation (including usability)** adequately described

MDCG 2019-16

Guidance on Cybersecurity for medical devices:



Areas covered:

- Introduction/Objectives/Trace to requirements in Regulations
- Basic Cybersecurity Concepts
- Secure Design and Manufacture
- Documentation and Instructions for use
- Post-Market Surveillance and Vigilance
- Other Legislation and guidance

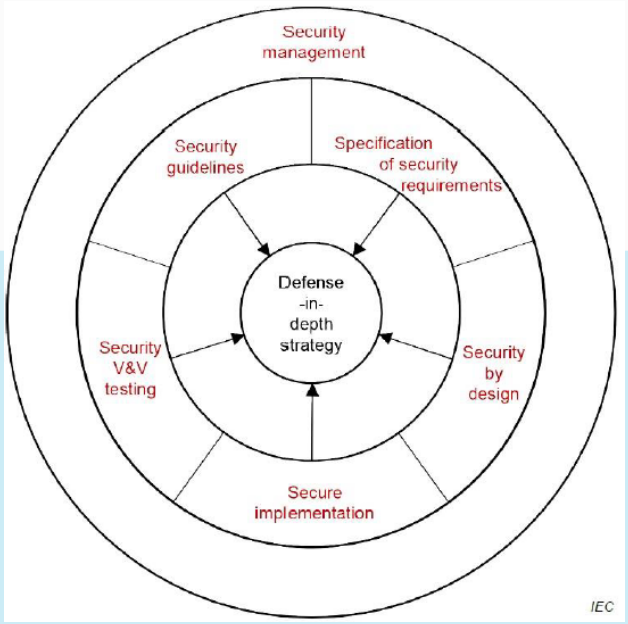
Table 1: Correspondence table between sections, relevant for this guidance, in MDR Annex I and IVDR Annex I

Main topic	Section number MDR Annex I	Section number IVDR Annex I
Device performance	1	1
Risk reduction	2	2
Risk management system	3	3
Risk control measures	4	4
Minimisation of foreseeable risks, and any undesirable side-effects	8	8
Combination/connection of devices/systems	14.1	13.1
Interaction between software and the IT environment	14.2.d	13.2.d
Interoperability and compatibility with other devices or products	14.5	13.5
Repeatability, reliability and performance	17.1	16.1
Development and manufacture in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation	17.2	16.2
Minimum IT requirements	17.4	16.4
Unauthorised access	18.8	-
Lay persons	22.1	-
Residual risks (information supplied by the manufacturer)	23.1 g	20.1 g
Warnings or precautions (information on the label)	23.2 m	20.2 m
Residual risks, contra-indications and any undesirable side-effects, (information in the instructions for use)	23.4 g	-
Minimum IT requirements (information in the instructions for use)	23.4.ab	20.4.1.ah

MDCG 2019-16

Key points:

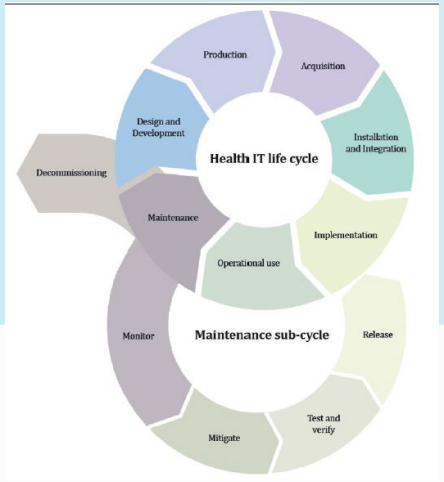
- Is security integrated with the development and risk management processes? ➔ Should not be “bolted on” at the end!
- Is there a security risk management plan?
- Is there a security risk assessment? ➔ Should minimally consider threats to Confidentiality, Availability, Integrity
- Has security-focused V&V testing been conducted? E.g.:
  - Security feature testing
  - Fuzz testing
  - Vulnerability scans
  - Penetration testing
- Are security mitigations captured in requirements?
- Are necessary IT/security requirements established in the IFU?
- Does the PMS/Vigilance process incorporate vulnerability and security incident monitoring
  ➔ Common Vulnerabilities and Exposures
- How are security updates & patches applied to SW in the field?

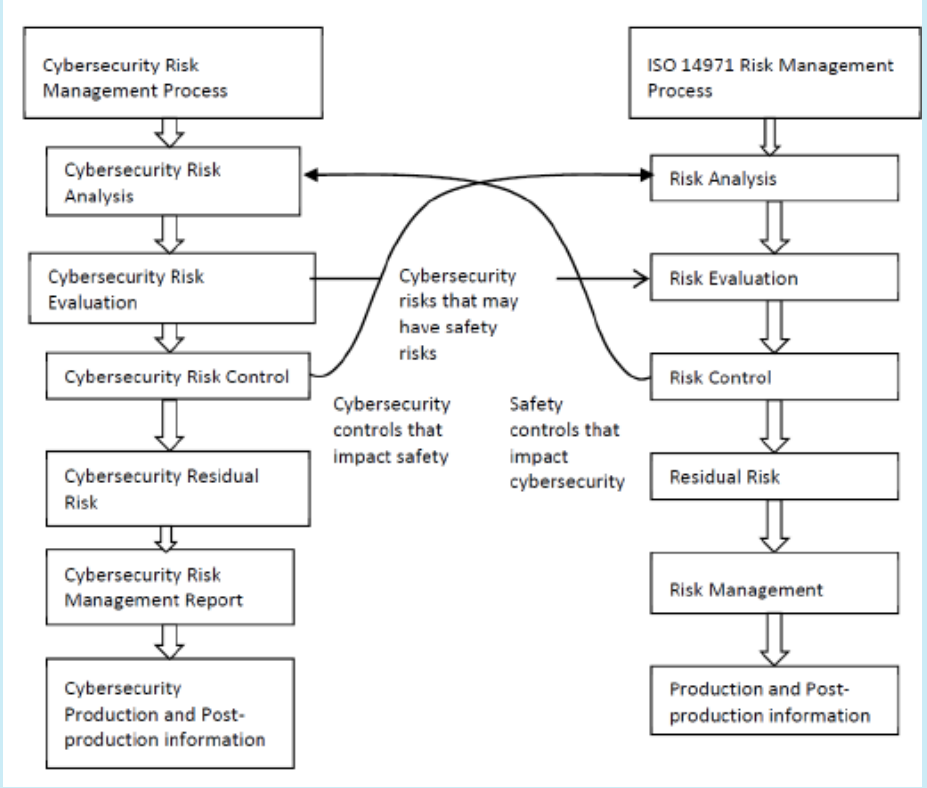


MDCG 2019-16

Key points:

- Cybersecurity risk management can affect safety risk management (and *vice versa*)
- Both processes should include monitoring in the post-production phase to identify elevated risks and take appropriate action when needed.
- Cybersecurity risk assessment should be updated based on information from the post-production phase.
- Patches/updates to address security concerns could be in the MDSW itself or in SOUP components (operating system, libraries, etc.)





UDI assignment to Medical Device Software MDCG 2018&5

Significant changes

Scope of UDI requirements for software

In accordance with **Annex VI, Part C** of the Medical Device Regulation (EU) 2017/745 (MDR) and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR), ***only software which is commercially available on its own as well as software which constitutes a device in itself shall be subject to UDI requirements.***

Changes to UDI-DI

In accordance with **Annex VI Part C, Section 6.5 of the MDR** and Section 6.2 of the IVDR, *a* ***new UDI-DI is required whenever there is a modification that changes the original performance, the safety of the software or the interpretation of data.*** *Such modifications include* ***new or modified algorithms, database structures, operating platforms, architecture, user interfaces and new channels for interoperability.*** Such changes would be considered **"significant."**

UDI assignment to Medical Device Software MDCG 2018&5

Changes

Any **change of the Basic UDI-DI**

Any changes which impact the original **performance**, **safety**, or the **interpretation of data**

A change to the **name or trade name**, **version or model number**, **critical warnings or contra-indications**, **user interface language** would require a new UDI-DI.

This is to guarantee the **traceability and correct identification** of the medical device software.

Minor Software Revisions

In accordance with **Annex VI, Part C, point 6.5.4** of the MDR and Annex VI, Part C, point 6.2.4 of the IVDR, **minor software revisions require a new UDI-PI and not a new UDI-DI**.

Minor software revisions are generally associated with **bug fixes**, **usability enhancements** that are **not for safety purposes, security patches or operating efficiency**. Minor software revisions shall be identified by a defined manufacturer-specific form of identification.

MDCG 2023-4 Medical Device Software (MDSW)

Hardware combinations - Guidance on MDSW intended to work in combination with hardware or hardware components

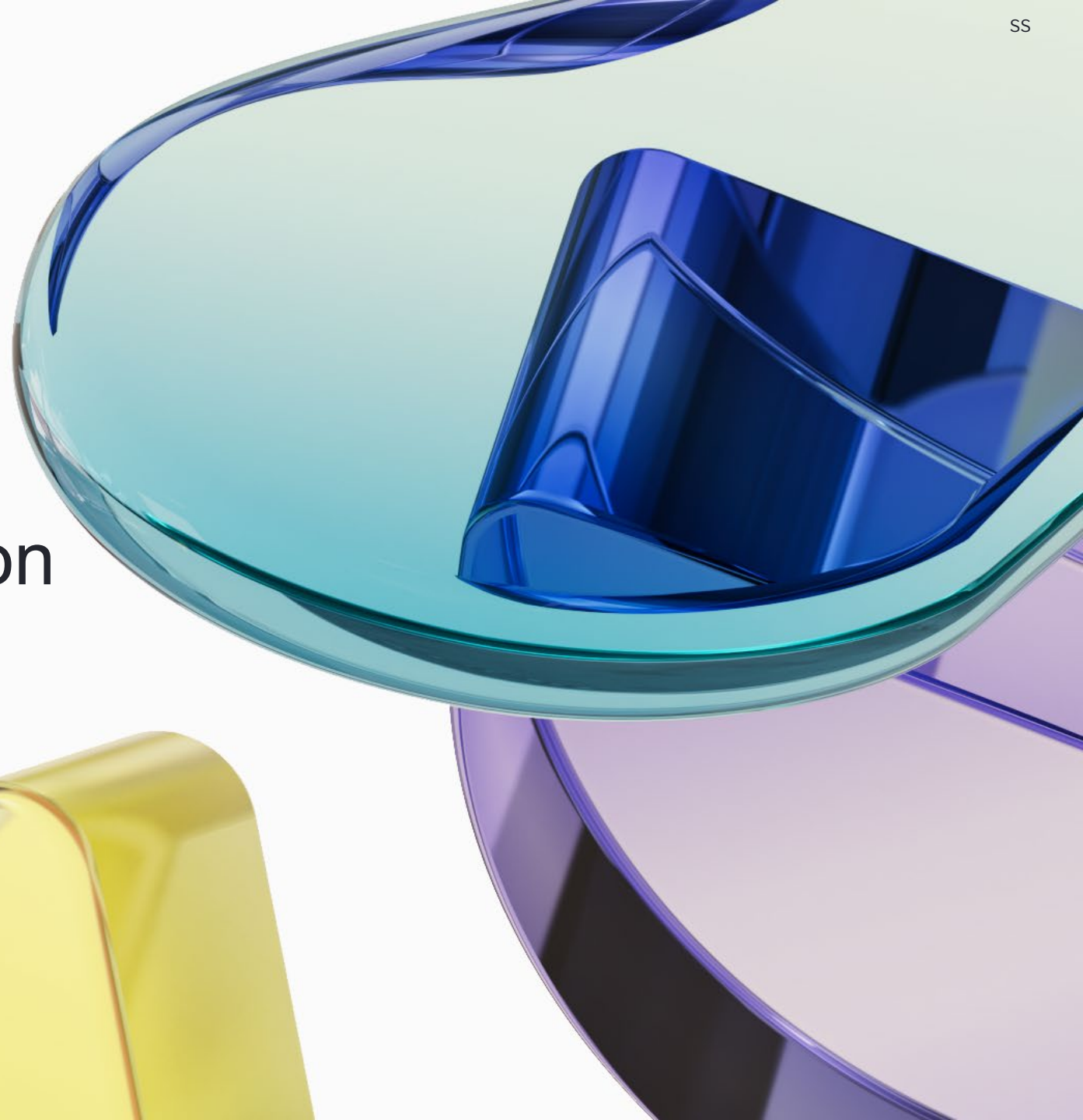
Considerations

In many cases, MDSW can **only achieve its intended purpose when it is used in combination with a hardware** or **hardware component (e.g., sensor)** generating or providing input data. For example, MDSW downloaded or available on **wearables (e.g. bracelets, smartwatches, virtual/augmented reality goggles)** to prevent, **predict or manage a disease, achieve their intended purpose** by receiving and analysing data provided by a hardware or hardware component. In these cases, **relevant hardware often incorporate components such as sensors and cameras**, the information from which may be used in a variety of MDSW, including so-called medical device applications (MDSW apps).

Sensors or other hardware components are in **certain cases integral parts** of general-purpose consumer electronics or wearable digital products. The **interaction between the MDSW, hardware or hardware component** (in particular integrated sensors) raise the question regarding the **qualification and the appropriate regulatory pathway or conformity assessment** of these hardware or hardware components.

The **intended medical purpose** of such MDSW apps **can only be achieved** through the use of hardware or hardware components that **demonstrate sufficient performance, accuracy and reliability, in light of the MDSW's intended purpose and the state of the art.**

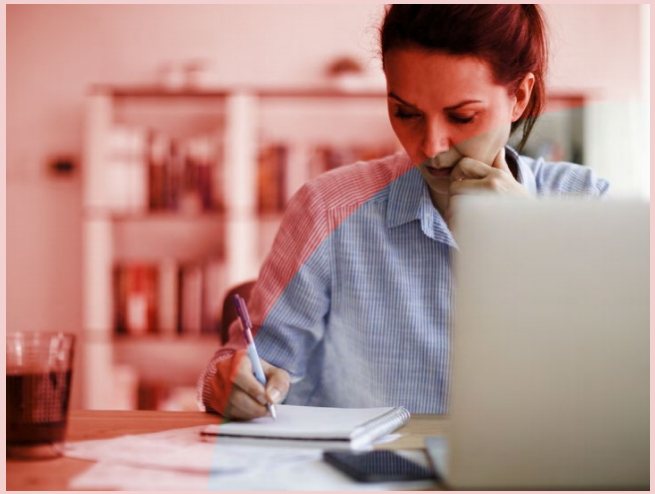
Technical file presentation



Technical file presentation

The most common reasons for delays in technical documentation reviews

- **Incomplete Submissions** - all the information needed for the review not provided
- **Poor structuring** of Technical Documentation – information present but difficult to locate.



Quality of Technical Documentation

- The **quality and organisation** of the documentation provided by the manufacturer is the most impactful variable in predicting the **efficiency of product review** and its successful outcome.
- **Full coverage** of Annex II and Annex III of the MDR must be presented
- A **complete and well-organised** technical documentation file **decreases the time** and cost of the review.

Technical file presentation

Some of the Best Practices for Notified Body Software Submissions

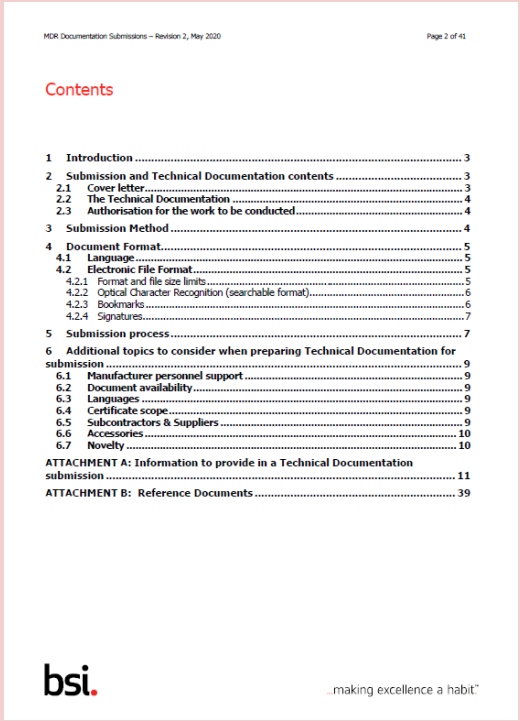
- NBs conduct detailed V&V and risk audits (sampling), so…
- **Trace matrices** should be provided (e.g. SW requirements to SW test cases)
- Risk management documents should allow **traceability from mitigations** - requirements and from requirements - V&V tests
- Technical auditors need to understand how the test operates - If automated tests are used, plain-language **summaries of the test sequence** and acceptance criteria are helpful.
- Raw data must be observed as part of the detailed audits
- Manual tests: Provide **test datasheets**
- Automated tests: **Provide execution/log files**

Technical file presentation

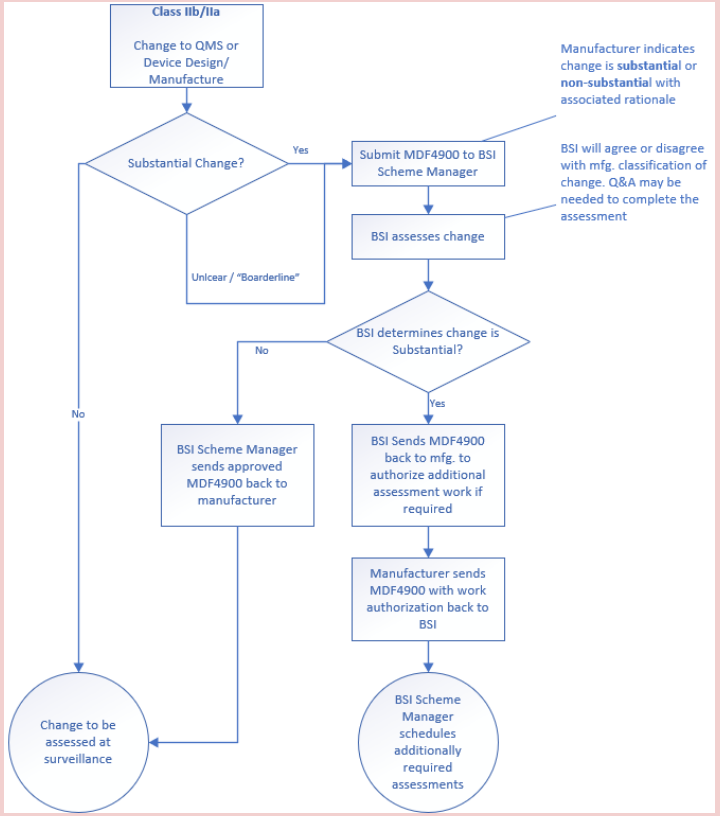
MDR Technical Documentation – Best Practice

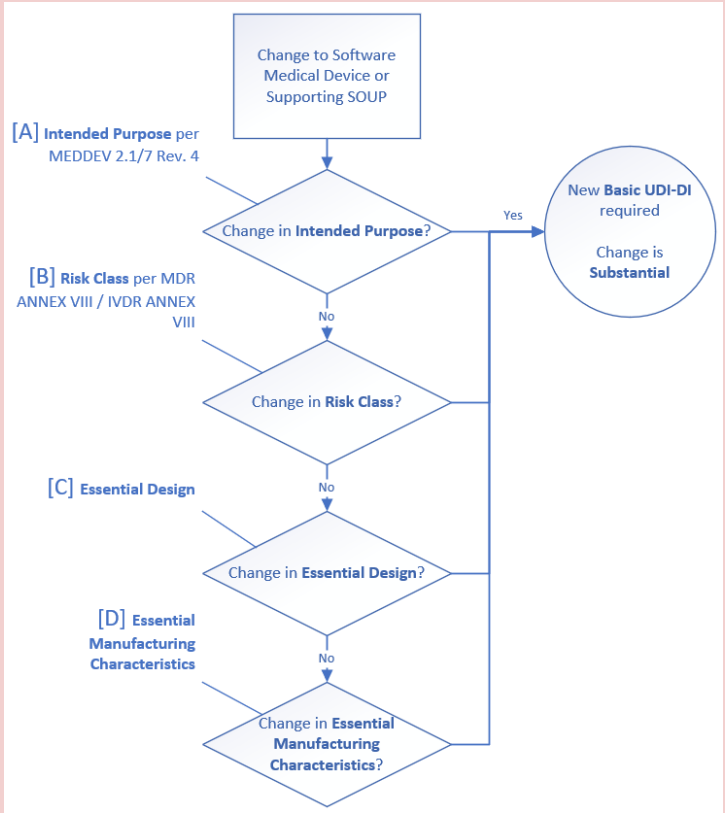
- **BSI provides this guide.**
- A complete and well-organised technical documentation file decreases time and cost of the review.
- Searchable, bookmarked PDF files
- The technical documentation should be available in full in accordance with Annex II and Annex III.

https://www.bsigroup.com/globalassets/meddev/localfiles/de-de/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf



Software changes– Technical file update.





- In general, **minor software revisions** require only an update to the UDI-PI of the software device and can be considered **non-substantial**
- MDCG 2018-5 states: *In accordance with Annex VI, Part C, point 6.5.4 of the MDR and Annex VI, Part C, point 6.2.4 of the IVDR, minor software revisions require a new UDI-PI and not a new UDI-DI. Minor software revisions are **generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.***
- Such changes will be assessed as part of ongoing technical documentation surveillance for class IIb/IIa devices.

Introduction to the SaMD Team

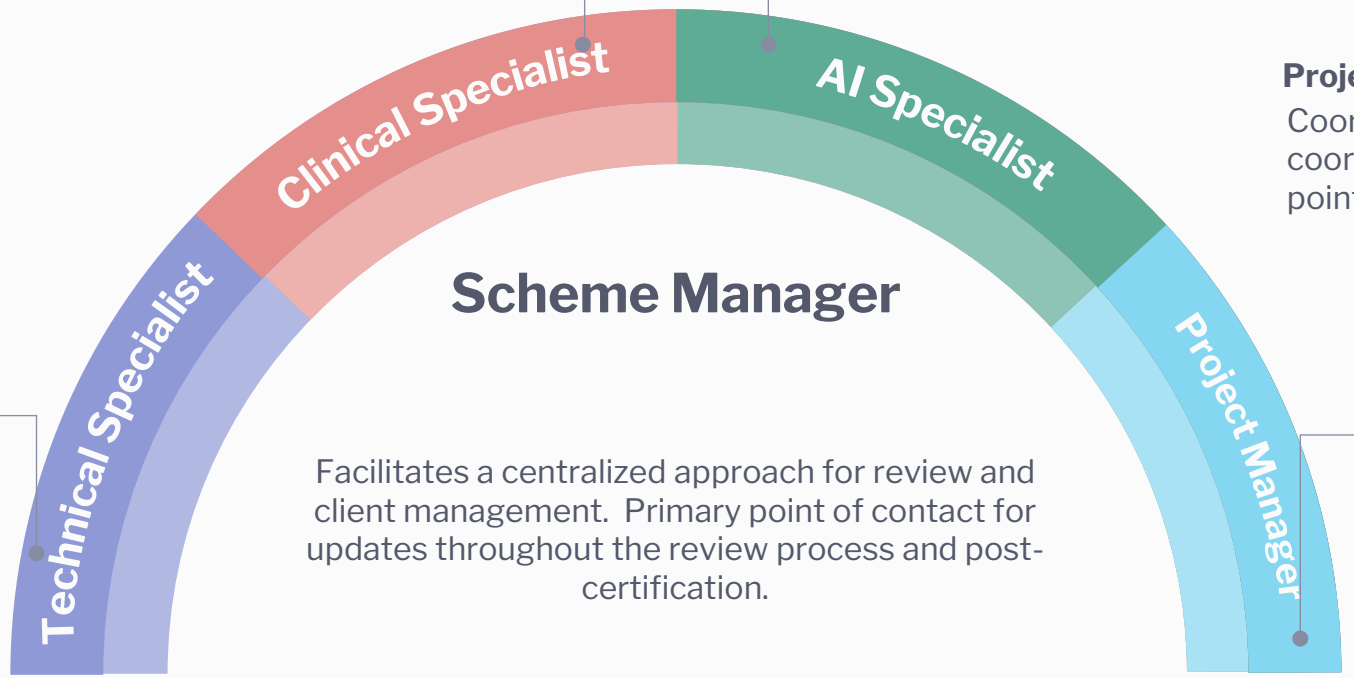
SaMD Review Team

Clinical Assessment
Focused on clinical documentation & assessment

Specialty Tech Assessments
Applicable only for devices that contain AI or are MRI compatible

Primary Reviewer
Focused on technical documentation and assessment

Project Manager
Coordinates scheduling of reviews and coordination of resources. Additional point of contact for review status.



Our Excellence Pathways

BSI CE and UKCA Excellence Programs are designed to support manufacturers seeking timely and effective market access. Our services combine efficiency with the integrity, independence, and the thoroughness you expect from BSI.

Standard

The Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert via phone and email as required.

Assignment of technical review	The Technical Review will be assigned based upon date of receipt of technical documentation
Opening the technical review	None
Scheduling rounds of review	Scheduling is round by round, upon receipt of a full and complete set of responses. The client is given an approximate start date
Review progress/questions	Questions are provided to the client at the end of each review
Closing a review round	List of questions provided to client

Dedicated

The Dedicated review service allows a technical document review to be booked in advance. It is conducted remotely with your BSI Product Expert, who uses your allocated time, to conduct a focused review of your technical documentation. This allows you to interact with your BSI Product Expert, and provide information during the review. By improving the efficiency of the process, this service provides predictability in your review planning.

Assignment of technical review	The Technical Review will be assigned before the client submits documentation based on readiness of the client
Opening the technical review	Opening meeting with the client
Scheduling rounds of review	Scheduling all rounds up-front. The client is given exact start dates. A minimum time between review tounds to allow for BSI to complete the review and for the manufacture to respond to questions raised
Review progress/questions	Questions are provided to the client throughout the review
Closing a review round	Closing meeting or email to client detailing remaining open questions

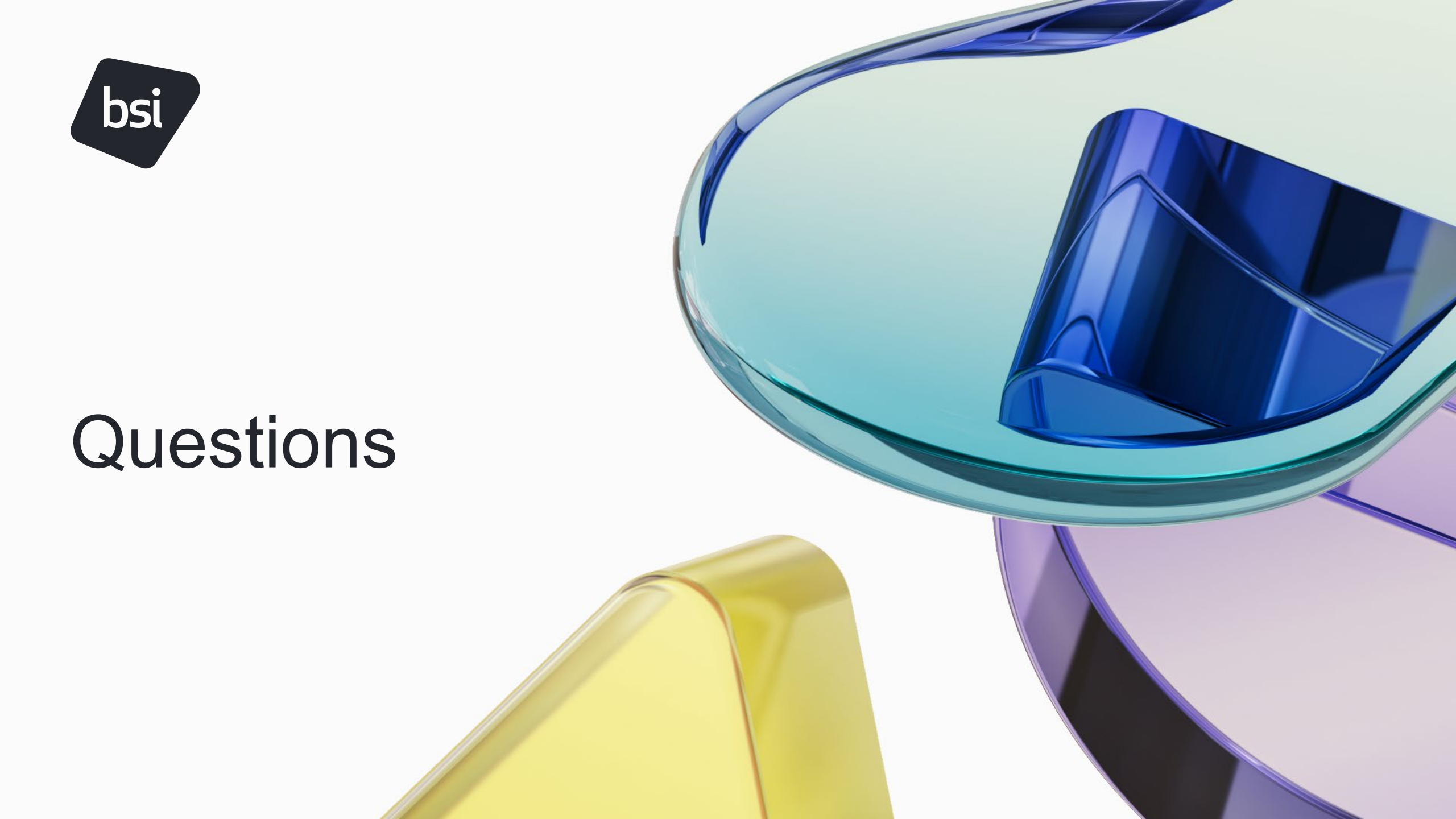
Note: Our services do not guarantee an EU/UKCA certificate will be issued or that it will be issued within a certain number of working days but they are based on completeing the review process with either a positive or negative recommendation. CE and UKCA Dediated Review service is not available for devices utilizing animal issue derivatives or medicinal substances.

Next Webinars :

Clinical evidence for Medical Device Software

Interplay between AI Act and the MDR

Questions



Thank you