Medicines & Healthcare products
Regulatory Agency

Digital Mental Health Technology - Regulation and Evaluation for Safe and Effective Products

Device characterisation, regulatory qualification and classification

Version 1.2

Contents

1. Glossary

AB	Approved body - A conformity assessment body appointed by a UK Competent Authority to undertake conformity assessment activities for the purposes of UKCA certification of products to be placed on the GB market
AI	Artificial intelligence
AR	Augmented reality
CBT	Cognitive behavioural therapy
CE certification	Certification that indicates a product's compliance with relevant EU regulations
DMHT	Digital mental health technology
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
DTAC	Digital Technology Assessment Criteria
DTC	Direct-to-consumer
EU	European Union
EU AIMDD	EU Directive 90/385/EEC on active implantable medical devices
EU MDD	EU Directive 93/42/EEC on medical devices
EU IVDD	EU Directive 98/79/EC on in vitro diagnostic medical devices
EU IVDR	EU *In Vitro D*iagnostic Regulation 2017-746
EU MDR	EU Medical Device Regulation 2017-745
GAD-7	Generalised Anxiety Disorder Assessment
GB	Great Britain
ICD-11	International Classification of Diseases – 11th revision
IFU	Instructions for use

IMDRF	International Medical Device Regulators Forum
JITAI	Just-in-time-adaptive intervention
MHRA	Medicines and Healthcare products Regulatory Agency
MR	Mixed reality
NB	Notified Body - A conformity assessment body appointed by an EU Competent Authority to undertake conformity assessment activities for the purposes of CE certification of products to be placed on the EU market
NHS	National Health Service
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
PHQ-9	Nine-item patient health questionnaire
PROMs	Patient reported outcome measures
SaMD	Software as a medical device
SNOWMED CT	Systematized Nomenclature of Medicine Clinical Terms
tDCS	Transcranial direct current stimulation
UK	United Kingdom
UKCA certification	Certification that indicates United Kingdom Conformity Assessed
UK MDR	UK Medical Device Regulations 2002 (SI 2002 No 618, as amended)
VR	Virtual reality
WSAS	Work and social adjustment scale
WHO	World Health Organisation

2. Development of this guidance

This guidance was developed as part of a Wellcome funded project, led by the Medicines and Healthcare products Regulatory Agency (MHRA) in partnership with the National Institute for Health and Care Excellence (NICE), focusing on clarifying the regulation and evaluation of digital mental health technology (DMHT)The project webpage can be accessed here. The guidance was developed after extensive stakeholder engagement via the project working group (including representatives from MHRA, NICE, NHS England policy, varied clinicians, health innovation network and lived experience) and roundtables with healthcare professionals, industry, United Kingdom (UK) approved bodies and international regulators.

3. Application of this guidance

This guidance is applicable to DMHTs placed on the UK market. This includes Great Britain (GB: England, Wales and Scotland) and Northern Ireland (NI).

It explains the regulation and evaluation of DMHT to ensure only safe and effective products are made available in the UK. Some DMHTs qualify as software as a medical device (SaMD) so must comply with relevant medical device regulations. This guidance explains how to determine this and how UKCA / CE certification shows compliance with these regulations.

In Great Britain, UKCA certification for medical devices is based on compliance with the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR) which give effect in UK law to three European Union (EU) directives:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD);
- Directive 93/42/EEC on medical devices (EU MDD);
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD).

At the MHRA, we are undertaking a programme of regulatory change to improve patient safety, give patients access to the medical devices they need and ensure the UK remains an attractive market for medical technology innovators. More information about the development of the regulatory framework, can be found here: ‘Implementation of the future regulations’. In addition, CE certification for medical devices is currently accepted on the GB market in line with the timelines set out in the above guidance.

In Northern Ireland, CE certification for medical devices is based on compliance with the EU Medical Devices Regulation (2017/745) (EU MDR) or the EU in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR).

For more information on the regulation for medical devices in GB and NI, please see MHRA guidance on regulating medical devices in the UK (2022).

4. DMHTs

DMHT are digital and software products that support mental health and wellbeing.

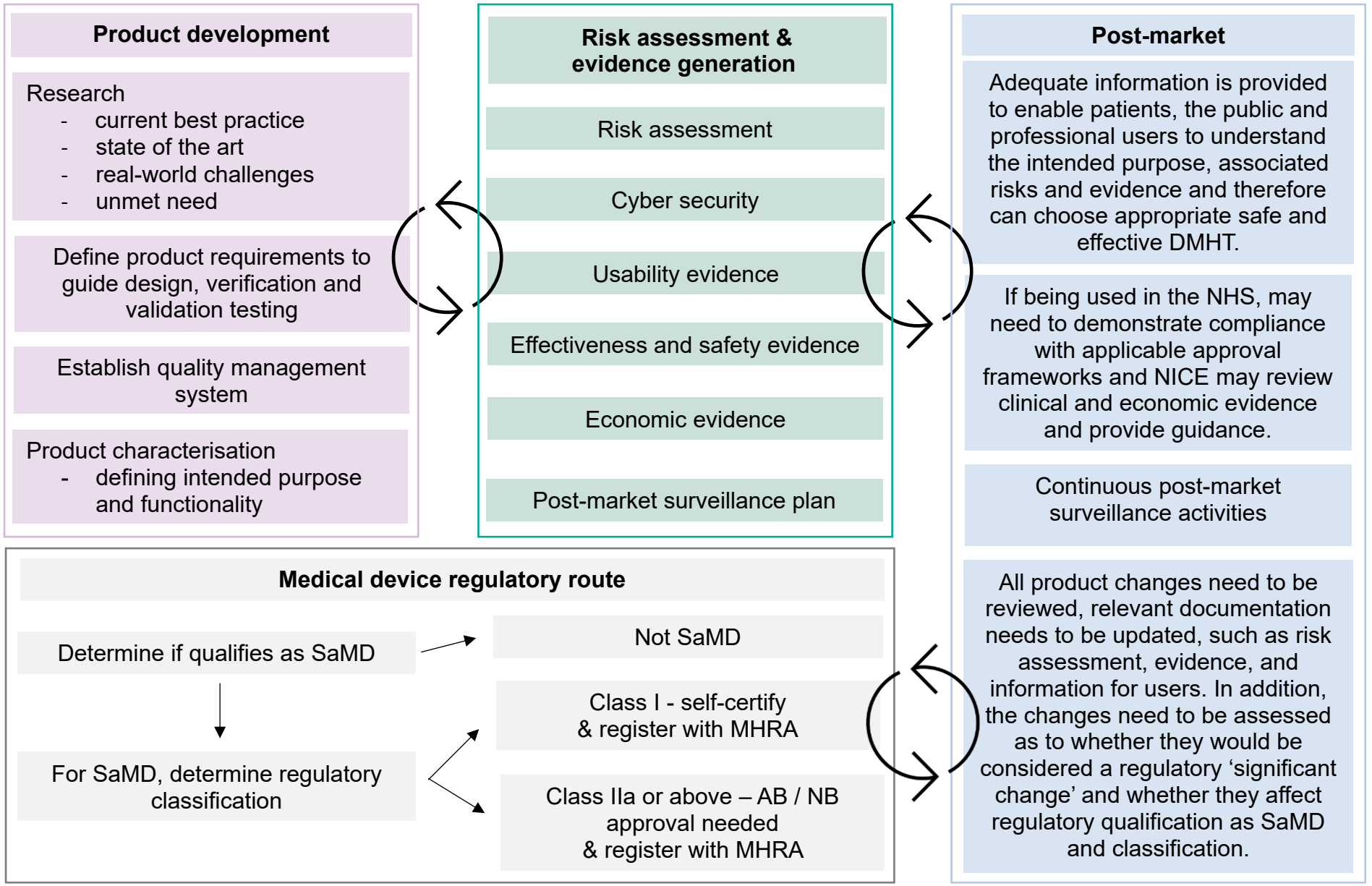
There are a wide range of different types of DMHTs. They can be websites, internet-based platforms or applications (apps) to be used with non-medical technology, such as computers, mobile phones, fitness wearables, and virtual reality (VR) headsets, or medical technology, such as transcranial direct current stimulation (tDCS) headsets. They can be available as direct-to-consumer products intended for patients and the public, often accessible through app stores for free or for a fee, or used with a referral or supervision from healthcare or educational professionals, as part of the blended delivery of mental health care.

Figure 1 illustrates some of the key steps in developing safe and effective DMHTs and emphasises that these steps are iterative across the lifecycle of the product.

The purpose of this guidance is to provide further information about three of the steps in Figure 1:

- Device characterisation – defining intended purpose and functionality;
- Determining qualification as software as a medical device (SaMD);
- Determining regulatory classification.

Figure 1. Key steps in developing effective and safe DMHT ready for widespread adoption.



5. Device characterisation

Device characterisation – defining intended purpose and functionality - is an important step as part of product development and helps with all subsequent steps such as determining qualification as SaMD, risk assessment, evidence generation and market adoption.

It is important to highlight that the device characterisation (intended purpose and functionality) will inform the type of clinical evidence required. The clinical evidence obtained may in turn affect your device characterisation. For instance, there should be consistency with the intended purpose and functionality of a device within the clinical studies and its application in real world settings. Further, if the clinical evidence demonstrates that there is a contraindication in a particular population group, the device characterisation needs to be updated to reflect this.

MHRA guidance on creating an intended use statement and International Medical Device Regulators Forum (IMDRF) Medical Device Software: Considerations for Device and Risk Characterization give guidance on how manufacturers can define and communicate device characterisation in a consistent and useful manner.

It is the manufacturer's responsibility to ensure that the intended purpose is clearly and consistently defined and communicated to potential users and other stakeholders in the labelling, instructions for use (IFU) and promotional materials (e.g. websites, social media and adverts) and technical documentation. This can be assessed by checking the understanding of typical users and monitoring how a product is actually being used.

The MHRA DMHT characterisation form (Appendix 1) can be used by manufacturers to define and communicate device characterisation to the MHRA (and other stakeholders) and needs to be completed if you are raising a regulatory query with the MHRA with reference to a specific DMHT.

6. Determining qualification as SaMD

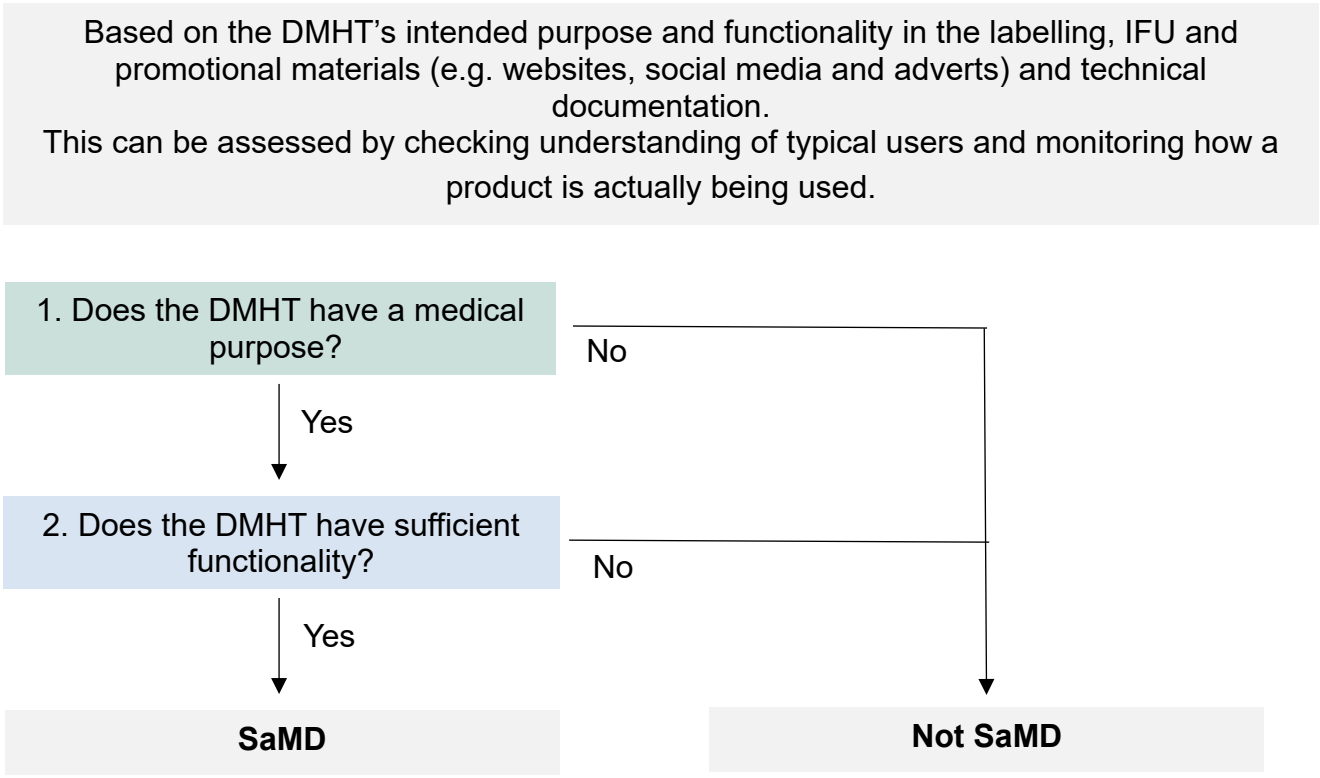
Determining whether a DMHT qualifies as SaMD is based on the intended purpose and functionality of the device in the labelling, IFU and promotional materials (e.g. websites, social media and adverts) and technical documentation. This can be assessed by checking the understanding of typical users and monitoring how a product is actually being used.

Figure 2 summaries the process and two main questions for determining whether a DMHT qualifies as SaMD and the following sections (6.1 and 6.2) provide further guidance on how to answer these questions along with examples. In both situations, when a DMHT qualifies as SaMD or does not qualify as SaMD, please review section 7 to understand how multi-

modular, interconnected DMHTs, accessories and systems can be regulated. If a DMHT does not qualify as SaMD, it may be considered a **component or accessory to another medical device or part of a system that makes up a medical device and therefore is still covered by the medical device regulations**.

It is important to note that this guidance provides a number of examples with a range of intended purposes and functionalities, but this is not an exhaustive list. It is recommended that the spirit of the guidance is applied when determining if a product qualifies as SaMD. If in doubt and after full consideration of this guidance, enquiries can be sent to the MHRA customer service centre (info@mhra.gov.uk) who may pass this on to the MHRA software team.

Figure 2. Summary of process for determining DMHT qualification as SaMD.



6.1. Does the DMHT have a medical purpose?

6.1.1. UK MDR, EU MDD & EU MDR

In the UK MDR and EU MDD, medical devices are defined as any instrument, software or other material intended to be used for human beings for purposes including:

- **diagnosis, prevention, monitoring, treatment** or **alleviation** of **disease;**
- **diagnosis, monitoring, treatment, alleviation** of or **compensation** for an **injury;**
- **investigation, replacement** or **modification** of the **anatomy** or of a **physiological process;**

In the EU MDR, medical devices are defined as any instrument, software or other material intended to be used for human beings for purposes including:

- **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;**

Therefore, if a DMHT is intended for one or more of the above purposes, it would be considered to have a medical purpose. For further detail, please see the next section for MHRA guidance on medical purpose in the context of DMHT.

6.1.2. MHRA guidance on medical purpose in the context of DMHT

DMHT are considered to have a **medical purpose** if they are intended as part of the **broad process** involved in the **management** of **mental ill health.**

This includes DMHTs that:

- help with **assessing risk, diagnosing, predicting, monitoring, treating** or **preventing** mental health **conditions and / or symptoms;**
- where the conditions and / or symptoms are at levels considered **diagnosable** or **clinically** relevant;

- and are either intended for **patients,** the **public** and / or **healthcare professionals.**

Figure 3 summarises and breaks down the process for determining when a DMHT has a medical purpose into two steps:

1) **Does the DMHT perform a clinical task?**
   Table 1 provides examples of DMHT clinical tasks covered by each EU MDD medical device definition term.

2) **Does the DMHT target clinical conditions and symptoms?**
   Table 2 provides further explanation and examples of targeted clinical conditions and symptoms covered by the EU MDD medical device term ‘disease’.

Please note, these tables provide guidance and examples but are not an exhaustive list.

Figure 3, Table 1 and 2 should be reviewed together to help determine whether a DMHT would be considered to have a medical purpose. For instance, if a DMHT ‘tracks’ health data with a ‘clear sports mental performance goal’ and no inferred medical benefit, it could be considered to be undergoing a clinical task covered by ‘monitoring’ in the EU MDD medical device definition, but it would not be considered to be targeting a clinical condition or symptom, therefore would not be considered to have a medical purpose. Conversely, if a DMHT ‘tracks’ ‘anxiety levels’ over time, it would be considered to be undergoing a clinical task covered by ‘monitoring’ in the EU MDD medical device definition and it would be considered to be targeting a clinical condition or symptom, therefore would be considered to have a medical purpose.

Figure 3. Summary of process for determining when DMHT has a medical purpose.

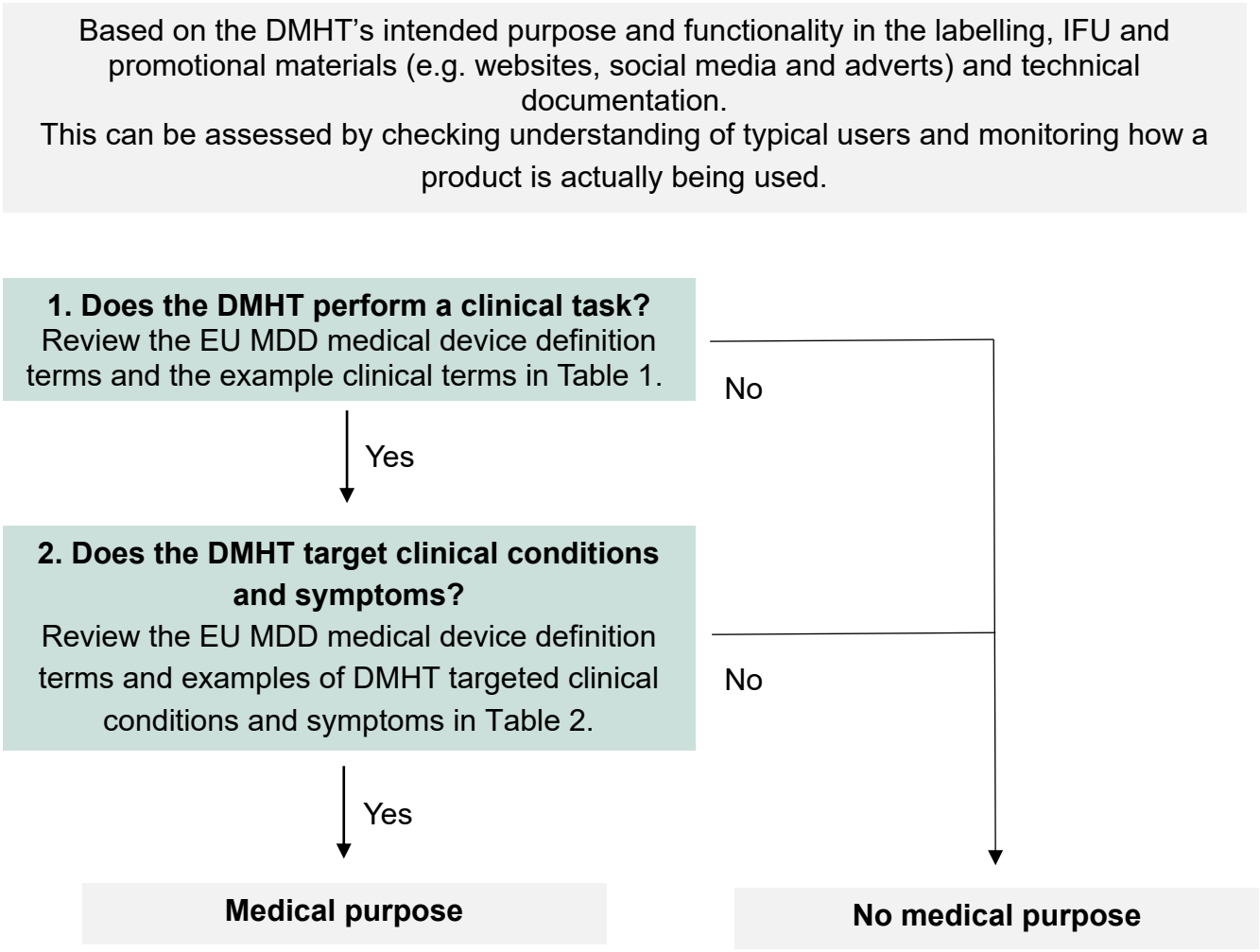


Table 1. EU MDD medical device definition terms and examples of corresponding DMHT clinical tasks.

EU MDD, medical device definition terms:	Examples of DMHT clinical tasks that are likely covered by the EU MDD medical device definition terms
'Diagnosis'	- Helps determine initial / indicative / working / full diagnosis - Enables self-assessment, symptom checker - Risk assesses, profiles, triages, screens - Provides health information, measures, calculates, scores - Clinical decision support - Predicts, estimates, provides prognosis
'Monitoring'	- Monitors, tracks - Presents progress, creates graphs - Detects, flags, alarms, indicates severity, provides prioritisation
'Treatment or alleviation'	- Treats, blended therapy, self-guided / directed therapy, digital CBT, AI therapist - Virtual / augmentative / mixed reality therapy - Recommends therapeutic options, clinical decision support - Psychoeducation, builds knowledge and skills - Enables parents to support their children
'Compensation'	- Supports, mitigates, reduces
'Prevention'	- Prevents, reduces likelihood - Psychoeducation, builds knowledge and skills

Table 2. EU MDD medical device definition term and examples of corresponding targeted clinical conditions and symptoms.

EU MDD, medical device definition term:	Examples of DMHT targeted clinical conditions and symptoms that are likely covered by the EU MDD medical purpose term
'Disease'	Includes DMHTs targeting conditions and associated symptoms according to established frameworks such as but not limited to WHO ICD-11, SNOWMED CT, and DSM-5, and standardised measures such as but not limited to PHQ-9, GAD-7 and WSAS.
	Includes DMHTs that reference the full medical term and those that do *not* reference the full medical term but infer this (see Note 1 below). For example, includes DMHTs that state they are intended for those with 'major depressive disorder'. In addition, includes DMHTs that state they are intended for those experiencing 'symptoms of depression' or 'low mood' if it is inferred this could include those with a formal diagnosis or those who are experiencing levels of symptoms that could be considered diagnosable or clinically relevant.
	Includes DMHTs that target a trans-diagnostic symptom if it is inferred it could be used by those with a formal diagnosis or those who are experiencing levels of the symptoms that could be considered diagnosable or clinically relevant (see Note 1 below). For example, includes DMHTs that target worrying if it is inferred this could include those with a formal diagnosis of an anxiety disorder or those who are experiencing levels of symptoms that could be considered diagnosable or clinically relevant.
	Includes DMHTs that are intended for general trans-diagnostic purposes. For example, includes DMHTs that predict risk of relapse / crisis.
	Includes DMHTs that target symptoms at levels considered at a well-being / sub-clinical level for those with another diagnosed medical condition. For example, targets low mood at sub-clinical levels for people with cancer.

Note 1:
Aspects of DMHTs that infer it is intended for those experiencing conditions and symptoms considered diagnosable or clinically relevant include:

- Its labelling, IFU and promotional materials (e.g. website, social media and adverts) point towards it being used in this manner.

- It includes standardised measures such as PHQ-9 or GAD-7 and individuals with all scores can continue to use the DMHT.

- It is used or recommended as part of an NHS service.

6.1.3. MHRA DMHT examples to illustrate what is considered as a medical purpose

Below are MHRA examples of intended purpose statements for a DMHT targeting symptoms at a **sub-clinical / well-being** level and a DMHT targeting symptoms at clinical levels as part of **one / many clinical conditions.**

Example 1 - **well-being** and does **NOT** have **medical purpose**
This product supports treatment of poor sleep. It is only for **well-being** and when poor sleep would be considered at **sub-clinical** levels, rather than **clinical levels** as part of a **diagnosable mental health condition.**

(N.B. other aspects do not infer that this product is intended for those experiencing conditions and symptoms considered diagnosable or clinically relevant – see Table 2 Note 1).

Example 2 - **well-being AND** has **medical purpose**
This product supports treatment of poor sleep which may be at **sub-clinical** levels or clinical levels as part of a **diagnosable mental health** condition such as insomnia disorder, major depressive disorder or generalised anxiety disorder.

Below is an MHRA example of an intended purpose statement for a DMHT aimed at **sub-clinical / well-being** symptoms but has claims that it **prevents** mental health conditions.

Example 3 - **prevention of mental health conditions** therefore has a **medical purpose**
This product helps improve sleep and can **prevent common mental health conditions** such as depression and anxiety.

Below is an MHRA example of an intended purpose statement for a DMHT aimed at **sub-clinical / well-being** symptoms for those with **another diagnosed medical condition** and it indicates that this would be considered to have a medical purpose as it is specifically for those with a diagnosed medical condition.

Example 4 - **well-being** for patients with another **diagnosed medical condition** therefore has a **medical purpose**
This product reduces **stress** for those with **epilepsy.**

Below is an MHRA example of an intended purpose statement for a DMHT where the intended users are the parents of children and young people who are experiencing a mental health condition or symptoms considered diagnosable or clinically relevant.

Example 5 - **intended user parent / carer with a medical purpose**
This product enables **parents / carers** to help their children manage **anxiety conditions** with the support of a healthcare professional.

Below is an MHRA example of an intended purpose statement for a DMHT that states it is only for well-being, however other aspects infer that it is intended for those experiencing conditions and symptoms considered diagnosable or clinically relevant – see Table 2 Note 1.

Example 6 – **inferred medical purpose**
On the manufacturer's website, it states that the product is designed to support individuals to improve their well-being. However, on the manufacturer's social media it promotes the product to suggest it **reduces** the risk of developing **depression** and / or the app is regularly **recommended by healthcare professionals in primary care** to help those with moderate depression.

The manufacturer should either:
1) Regulate this product as a medical device, ensuring there is consistent messaging around its intended use and evidence.
2) Should remove any inferences to mental health conditions on social media and elsewhere and ensure it is not being recommended by healthcare professionals or being used for a medical purpose.

Below are some other MHRA examples of DMHT that do **not have a medical purpose.**

Examples 7-10 - **no medical purpose**
Products that use aggregated population level data to output mental health intelligence that can be useful for **planning provision** at a local level or **service evaluation** (e.g. using Mental Health - OHID (phe.org.uk))

Products that are related to **sport performance** are usually not considered to have a medical purpose.

Products that are intended to only provide **education** for healthcare professionals.

Products that provide **healthcare administration support** only (e.g. booking an appointment, requesting a prescription).

6.2. Does the DMHT have sufficient functionality?

6.2.1. UK MDR, EU MDD & EU MDR

EU guidance for the EU MDD (EU MEDDEV 2.1/6 Qualification and classification of stand lone software (2016)) and EU guidance for the EU MDR (EU MDCG 2019-11 Rev 1 Guidance on qualification and classification of software in regulation (EU) 2017/745 - MDR and IVDR (2019)) both highlight in their respective Figure 1 step 3 that a software needs to be 'performing an action on data different from storage, archival, communication or simple search' in order to be covered by the medical device regulations.

MHRA guidance on SaMD highlights this in some of the examples too. For example, on slide 12 it states that if a software 'just reproduces a paper document in digital format' it is unlikely a medical device. In addition, on slide 40 it explains that if a software is only performing a simple and easily verifiable calculation it may not qualify as SaMD.

6.2.2. MHRA guidance on functionality in the context of DMHT

Figure 4 and Table 3 take the concepts in the EU and MHRA guidance and provides a method and visualisation, as well as clarity on how this can be applied for DMHTs.

Figure 4 and Table 3 illustrate that DMHTs can be divided into functions and within these functions there can be one or many computational tasks. If a function only performs computational tasks such as A-D in Figure 4, it would be considered low functionality. If a function performs computational tasks other than those described in A-D, such as those described in E-F in Figure 4, it would be considered high functionality. Those functions that have a medical purpose and high functionality are likely to be SaMD and the manufacturer can regulate each function as separate SaMD or join many functions together and regulate as one SaMD. This will be described further in subsequent sections of this guidance.

Please note that the MHRA guidance on SaMD section on calculators that are easily verifiable has been translated into category '*D. Processes data / information with an easily verifiable calculation / algorithm*' and we have clarified what requirements are needed to be met in order to be able to use this category in note 1. It is also important to note that as this comes from MHRA guidance as opposed to EU guidance, you can only use this category if you are obtaining a UKCA certification, as opposed to a CE certification.

Figure 4. Summary of how DMHT can be categorised into functions and computational tasks and considered low / high functionality which impacts qualification as SaMD.

What are the DMHT functions and computational tasks?

Functions: e.g. e-coach, questionnaires, graphs, fixed content psychoeducation, interactive and personalised content, triage, AI chatbot

If the function **only** performs one or more of the following computational tasks it is considered **low functionality**:

A. **Stores** data / information **without** change

B. **Communicates** data / information **without** change or prioritisation

C. **Processes user instruction** to show **fixed content** in a similar manner to a user choosing a chapter in a digital book, audio book or video

D. **Processes** data / information with an **easily verifiable** calculation / algorithm (Note 1)

If the function performs computational tasks (other than A-D on the left), such as the following, it is considered **high functionality:**

E. **Processes user instruction** with an **interactive** and / or **personalised** output

F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable

G. **Processes** data / information using **AI**

Medical purpose + low functionality = not SaMD
Medical purpose + high functionality = **SaMD**

Note 1:
A computational task can only be considered as category
'*D. Processes data / information with an easily verifiable calculation / algorithm*'
if the following points are **all** met:

1) Information is provided to the user about what the tool is intended for and what its limitations are.

2) Information is provided to the user about how the tool has been developed and validated.

3) Information is provided to the user about how the tool works that is understandable for intended users.

4) The tool is presented to the user in a manner that makes it easily verifiable.

5) There is signposting for further information if the user needs it.

6) User studies have been undertaken and provide evidence that a typical user understands the information detailed in 1-5 above and can reliably detect whether a score is incorrect and check it, without additional aids such as a calculator, and is therefore easily verifiable for a typical user.

   When planning the usability testing, please review BS EN 62366-1:2015+A1:2020 Medical devices. Application of usability engineering to medical devices.

   In addition, please consider:

- the intended user's likely knowledge and skills (e.g. is the intended user a healthcare professional or patient / public? Is the intended user an adult, young person or child? May the intended users have any intellectual or physical disabilities, neurodivergence, impairment of mental capacity or be impacted by any other factors such as language that may affect how easily verifiable a tool is in the circumstance for which it is designed to be used?). The usability testing needs to be performed in a population that is representative of the intended user population.

- the typical use environment (e.g. is it intended to be used in a clinical time-pressured environment or at home with more time?). The usability testing needs to be performed in an environment that is representative of the intended use situation.

- Sample size. This will depend on the range of i) intended users ii) environments and iii) the complexity of the functionality.

- Please note, using user studies to determine whether a tool is easily verifiable is one type of user study. There should be further iterative user testing during product development to ensure that a tool is desirable, effective and safe.

If these cannot be met, the computational task would be considered as category
- *'E. Processes user instruction with an interactive and / or personalised output';*
- *'F. Processes data / information with a calculation / algorithm that is not easily verifiable'; or*
- *'G. Processes data / information using AI'.*

Table 3 – MHRA DMHT examples of functions, computational tasks and low / high functionality.

What are the DMHT functions and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 1 – user sign-in via fixed form			
User sign-in is enabled via questions on a fixed digital form, prompting the user to input their required personal data / information. Required: Name; Email address; Date of birth.	A. **Stores** data / information **without** change	User can see stored personal data / information.	Low
Function 2 – user sign in via generative AI			
User sign in is enabled via a generative AI chatbot asking the user questions, prompting the user to input the required personal data / information. Required: Name; Date of birth; Symptoms.	A. **Stores** data / information **without** change G. **Processes** data / information using **AI**	Generative AI chatbot responds to user's input in an appropriate manner depending on the content with the aim of creating a welcoming and compassionate environment whilst also collecting required personal data / information for sign in.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 3 – fixed digital content for psychoeducation			
User instruction – user can choose from 10 modules of fixed content for psychoeducation in the same way they could choose a chapter in a digital book, audio book or video. User can write down their thoughts or experiences in fixed digital worksheets that are similar to a digital version of a book with worksheets.	A. **Stores** data / information **without** change C. **Processes user instruction** to show **fixed content** in a similar manner to a user choosing a chapter in a digital book or audio book	User can read fixed text, listen to fixed audio, or watch fixed videos. User can refer back to saved completed digital worksheets.	Low
Function 4 – fixed digital content and interactive, personalised content for psychoeducation			
User instruction – user can choose to review fixed content for psychoeducation in the same way they could review a digital book, audio book and video. In addition, user can complete interactive and personalised content such as writing distressing thoughts on a leaf and watching it float down a river getting smaller in the distance.	C. **Processes user instruction** to show **fixed content** in a similar manner to a user choosing a chapter in a digital book, audio book or video E. **Processes user instruction** with an **interactive** and / or **personalised** output	User can read fixed text, listen to fixed audio, or watch fixed videos. User can interact with content.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 5 – e-coach messaging			
User interface enables user to text a message to an e-coach.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation	User's message is stored and communicated to e-coach interface without change or prioritisation. E-coach checks and responds to all messages with a text reply within 24 hours.	Low
Function 6 – e-coach progress tracker			
When a user completes a module, a green tick automatically appears by module heading on main page of the user interface.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation	This information is communicated to the e-coach interface without change or prioritisation so the e-coach can see when a user has completed a module.	Low

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 7 – e-coach with risk assessment			
User inputs responses to set questions throughout a psychoeducation module on user interface.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Software stores and communicates the user responses to the e-coach interface. In addition, software risk assesses the responses via an algorithm and provides the e-coach with a list of users who's responses were determined as high risk according to the algorithm and therefore who may need extra support. The e-coach does not check all the algorithm results as has many users therefore it is considered not easily verifiable.	**High**
Function 8 – simple peer-to-peer support forum			
User interface enables user to post a message on the peer-to-peer support forum about how they are feeling.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation	Message is saved on peer-to-peer support forum and other users can see it therefore it is saved and communicated without change or prioritisation. Other users can respond to message on the peer-to-peer support.	Low

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 9 – peer-to-peer support forum, risk assessment and e-coach			
User interface enables user to post a message on the peer-to-peer support forum about how they are feeling.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	An algorithm (that is not detailed to the users) checks every post before publishing. If the algorithm categories the post as low risk, the post is published automatically. If it categories it as moderate / high risk, an e-coach needs to check the post to determine whether it can be published in line with guidelines and whether the user needs extra support.	**High**
Function 10 – peer-to-peer support forum with AI categorising and filtering			
AI tags each post depending on assessment of subject, age limits and propensity to trigger distress. User can filter their dashboard so they can only see posts relevant for them via subject, age limits or triggering tag.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Due to AI tagging and large number of posts, human moderator or user can not verify that software has tagged and filtered correctly. If incorrect, user may potentially see posts that trigger distress.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 11 – AI transcriber and consultation summarisers			
Healthcare professional and patient consultation is recorded.	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation C. **Processes** data / information using **AI**	Generative AI converts speech to text transcript and then provides summary which is inputted into patient's electronic health record to help with decisions related to care. Healthcare professional may not have time to verify all summaries.	**High**
Function 12 – augmentative and alternative communication software			
Software input is speech from children with developmental language disorder.	D. **Stores** data / information **without** change E. **Communicates** data / information **without** change or prioritisation F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Software output is transcribed written information to help child communicate. It may not be clear when the software has made an error.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 13 – Nine-item patient health questionnaire (PHQ-9) which is easily verifiable			
User responds to the PHQ-9 questions in a fixed form.	D. **Processes** data / information with an **easily verifiable** calculation / algorithm	Software provides PHQ-9 results. It meets requirements for easily verifiable as per Figure 3 Note 1 and as shown in Example 11.	Low
Function 14 – Quiz which is easily verifiable			
User needs to answer a quiz to show whether they have understood psychoeducation material.	A. **Stores** data / information **without** change E. **Processes** data / information with an **easily verifiable** calculation / algorithm	Software provides results. It meets requirements for easily verifiable as per Figure 3 Note 1 and as shown in Example 12.	Low

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 15 – Digital diary and presenting data graphically			
User responds to PHQ-9 questions in a fixed form every 2 weeks.	A. **Stores** data / information **without** change D. **Processes** data / information with an **easily verifiable** calculation / algorithm	Software provides PHQ-9 results. It meets requirements for easily verifiable as per Figure 3 Note 1 and as shown in Example 11. In addition, software processes PHQ-9 results over time and presents them on a graph. It meets requirements for easily verifiable as per Figure 3 Note 1 and as shown in Example 13.	Low
Function 16 – Digital diary and presenting data graphically with means and standard deviations			
User responds to PHQ-9 questions in a fixed form every 2 weeks.	A. **Stores** data / information **without** change E. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Software processes PHQ-9 scores and presents them on a graph with a red flag for any results that fall above the standard deviation of the average enabling user to evaluate progress over time against the average. It does not meet requirements for easily verifiable as per Figure 3 Note 1.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 17 – Electronic mental health records			
Healthcare professionals input information for each patient into their individual patient record.	A. **Stores** data / information **without** change D. **Processes** data / information with an **easily verifiable** calculation / algorithm	Software allows healthcare professional to search for a particular patient via their NHS number or search for a particular appointment via date. It meets requirements for easily verifiable as per Figure 3 Note 1.	Low
Function 18 – Database with clinical risk assessment			
Information from patient records.	A. **Stores** data / information **without** change E. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Software shows information from patient records in an easy to view dashboard with key data such as when patient was last reviewed and their current medication. In addition, includes clinical risk assessment of patient based on a number of different inputs and this gives a priority rating for healthcare professional to review i.e. high-risk patients are prioritised for review.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 19 – Cognitive bias modification training - simple and understandable version			
Software provides scenarios with open ambiguous endings that could be interpretated with a paranoid or positive ending and the user is asked to imagine a positive ending and note this down.	A. **Stores** data / information **without** change	Software saves the user's responses.	Low
Function 20 – Cognitive bias modification training - complex version			
Software provides scenarios with open ambiguous endings that could be interpretated with a paranoid or positive ending and software asks users to imagine a positive ending and answer related questions.	A. **Stores** data / information **without** change E. **Processes user instruction** with an **interactive** and / or **personalised** output F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Depending on user's response, scenarios become more personalised – either more relatable to user's life (e.g. their work and hobbies) or more closely matches to areas of their life where negative / paranoid thoughts are triggered more often or where they find it harder to imagine a positive ending.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 21 – Healthcare professional triage clinical decision support			
Patient answers large number of personalised questions.	A. **Stores** data / information **without** change G. **Processes** data / information using **AI**	AI ensures questions are relevant for user and AI gives a report for healthcare professional showing likelihood of mental health conditions.	**High**
Function 22 – Symptom checker			
Individual answers questions.	A. **Stores** data / information **without** change F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Based on individual's responses, software gives a patient or member of the public a list of possible mental health conditions in order of likelihood.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 23 – Digital phenotyping			
Software monitors use of mobile phone.	A. **Stores** data / information **without** change F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable G. **Processes** data / information using **AI**	Software alarms when digital biomarker crosses a threshold which is considered to indicate potential risk of exacerbation of symptoms / relapse / crisis.	**High**
Function 24 – AI coach / companion / therapist			
User responds to AI coach / companion / therapist via text message.	F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable G. **Processes** data / information using **AI**	AI coach / companion / therapist responds based on user's replies in a compassionate manner. AI coach / companion / therapist may give personalised advice and suggest user completes certain modules / practices to help particular situation.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 25 – Just-in-time-adaptive intervention (JITAI) or closed loop interventions - easily verifiable version			
User responds to 3 basic questions about how they are feeling.	A. **Stores** data / information **without** change D. **Processes** data / information with an **easily verifiable** calculation / algorithm	Based on responses, software recommends intervention (e.g. you said you did not sleep well, therefore we recommend you review module on sleep hygiene).	Low
Function 26 – JITAI or closed loop interventions			
Software collects passive data (e.g. information from a smart watch such as sleep, activity levels, breathing rate, heart rate variability) and active data (e.g. information inputted by individual via responses to questions).	A. **Stores** data / information **without** change F. **Processes** data / information with a calculation / algorithm that is **not** easily verifiable	Based on passive and active data and complex calculations, software recommends interventions (e.g. exercise, sleep hygiene, socialising).	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 27 – Digital game			
Patient uses keyboard to move an avatar in a magical world where they come up against psychosocial challenges and have a wise owl to help guide them to develop CBT and DBT knowledge and skills.	E. **Processes user instruction** with an **interactive** and / or **personalised** output	Based on user's inputs, the game is played in different ways.	**High**
Function 28 – Virtual reality (VR) / augmented reality (AR) / mixed reality (MR)			
Healthcare professional chooses multiple options to create an interactive and personalised VR environment that will help patient with gradual exposure to feared situations and/or phobic stimuli in order to develop coping behaviours.	E. **Processes user instruction** with an **interactive** and / or **personalised** output	VR environment creation and VR environment adapts depending on patient's actions in VR environment.	**High**

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 29 – App influences or drives a transcranial direct current stimulation device			
User enters personal data / information.	A. **Stores** data / information **without** change F. **Processes data / information** with a calculation / algorithm that is **not** easily verifiable	Based on personal data / information, app uses calculation / algorithm to suggest programme of use of transcranial direct current stimulation device. In addition, app can directly influence / drive the settings of the transcranial direct current stimulation device.	**High**

Example 11 – PHQ-9 that is easily verifiable

Information is provided to the user about what the tool is intended for and the limitations

The nine-item patient health questionnaire (PHQ-9) is used to screen for depression but does not provide a formal diagnosis, only a qualified healthcare professional can do this, further to an extensive holistic assessment[1].

Information is provided to the user about how the tool has been developed and validated

The 9 questions are based on the criteria upon which the diagnosis of Diagnostic and Statistical Manual of Mental Disorders – 4th edition (DSM-IV) depressive disorders is based.

Studies have shown that it is a reliable and valid measure of depression severity. These characteristics plus its brevity make the PHQ-9 a useful clinical and research tool. For more information, please see www.phqscreeners.com[1].

It is validated for use in primary care in the NHS[2].

References:

1. The PHQ-9: Validity of a Brief Depression Severity Measure - PMC
2. Assessment | Diagnosis | Depression | CKS | NICE

Information is provided to the user about how the tool works that is understandable for intended users

It consists of 9 questions that ask about frequency of symptoms over the past 2 weeks. It classifies the self-reported current symptoms on a scale of 0 (not at all) to 3 (nearly every day). The maximum score is 27 and there are 5 resulting categories:

0-4 = no depression
5-9 = Mild depression
10-14 = Moderate depression
15-19 = Moderately severe depression
20-27 = Severe depression

The tool is presented to the user in a manner that makes it easily verifiable

User can easily review the questions, their answers, how their answers were scored, their result, and the meaning of their results as shown in the tables below.

Over the last 2 weeks, on how many days have you been bothered by any of the following problems:	Not at all (0)	Several days (1)	More than half the days (2)	Nearly every day (3)
1. Little interest or pleasure doing things		/ (1)		
2. Feeling down, depressed or hopeless		/ (1)		
3. Trouble falling or staying asleep, or sleeping too much			/ (2)	
4. Feeling tired or having little energy		/ (1)		
5. Poor appetite or overeating		/ (1)		
6. Feeling bad about yourself - or that you are a failure or have let yourself or family down			/ (2)	
7. Trouble concentrating on things, such as reading the newspaper or watching television				/ (3)
8. Moving or speaking so slowly that other people could have noticed, or the opposite – being so fidgety or restless that you have been moving around a lot more than usual		/ (1)		
9. Thoughts that you would be better off dead or of hurting yourself in some way	/ (0)			
PHQ-9 questionnaire total score	1 + 1 + 2 + 1 + 1 + 2 + 3 + 1 + 0 = 12			

PHQ-9 score	Meaning
0-4	No depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

User is signposted for more information
If user has any questions or concerns regarding the result, they are advised to contact a healthcare professional.

User studies have been undertaken and provide evidence that the tool is easily verifiable
User studies have been undertaken and provide evidence that a typical user understands the information and can reliably detect whether a score is incorrect and check it, without additional aids such as a calculator, and is therefore easily verifiable for a typical user.

Example 12 – Quiz that is easily verifiable

Information is provided to the user about what the tool is intended for and the limitations

This quiz is to help you learn and monitor progress of understanding of the psychoeducation material in modules 1-5. Don't worry if you do not get the correct answers first time, it can take time to learn new information and skills. If so, review the relevant module to check understanding and re-take at a later date. Although the quiz gives an indication of understanding of the psychoeducation material in modules 1-5, evidence has shown that the app is most effective when users can understand how this material applies to them in the real world. For example, they can identify when they are 'catastrophising' and reach for healthy tools to manage this. For more information, please see the evidence tab.

Information is provided to the user about how the tool has been developed and validated

This is a bespoke quiz created by the manufacturer of the app. It has not been specifically validated but there is evidence that using this app over a 6-week period can improve symptoms of depression. For more information, please see the evidence tab.

Information is provided to the user about how the tool works that is understandable for intended users

It consists of 20 multiple choice questions, where more than one choice can be correct. Once you press submit, your answers and the correct answers are shown, along with the module where you can find more information. At the end, it shows how many of the questions you got correct, out of 20. If you get any incorrect, we recommend you review the corresponding module and then re-take the quiz at a later date to see whether you can get 20 / 20.

The tool is presented to the user in a manner that makes it easily verifiable

User can easily review the questions, their answers, the correct answers, and where they can find the corresponding information as shown in the boxes below.

Which are common cognitive distortions / thinking errors? Tick all that apply.

Catastrophising ☑ Negative thinking ☑

Polarised thinking ☑ Mind-reading ☑

Correct – all these are common cognitive distortions / thinking errors!

For more information – see module 5.

OR

Which are common cognitive distortions / thinking errors? Tick all that apply.

Catastrophising ☑ Negative thinking ☑

Polarised thinking ☐ Mind-reading ☑

Almost – all of these are common cognitive distortions / thinking errors!

For more information – see module 5.

User is signposted for more information

If user has any questions or concerns regarding the result, they are advised to contact a healthcare professional.

User studies have been undertaken and provide evidence that the tool is easily verifiable

User studies have been undertaken and provide evidence that a typical user understands the information and can reliably detect whether a score is incorrect and check it, without additional aids such as a calculator, and is therefore easily verifiable for a typical user.

Example 13 - Digital diary and presenting data graphically that is easily verifiable

Information is provided to the user about what the tool is intended for and the limitations

This tool presents your PHQ-9 scores calculated every 2 weeks on a graph against time. For more information about the PHQ-9, please see here. If you click on one of the entries, you will be able to review your PHQ-9 answers for that week.

Information is provided to the user about how the tool has been developed and validated

For more information about how PHQ-9 was developed and validated, please see here. This tool of converting PHQ-9 sores onto a graph against time was created by the manufacturer of the app. It has not been specifically validated but there is evidence that using this app over a 6-week period can improve symptoms of depression. For more information, please see the evidence tab.

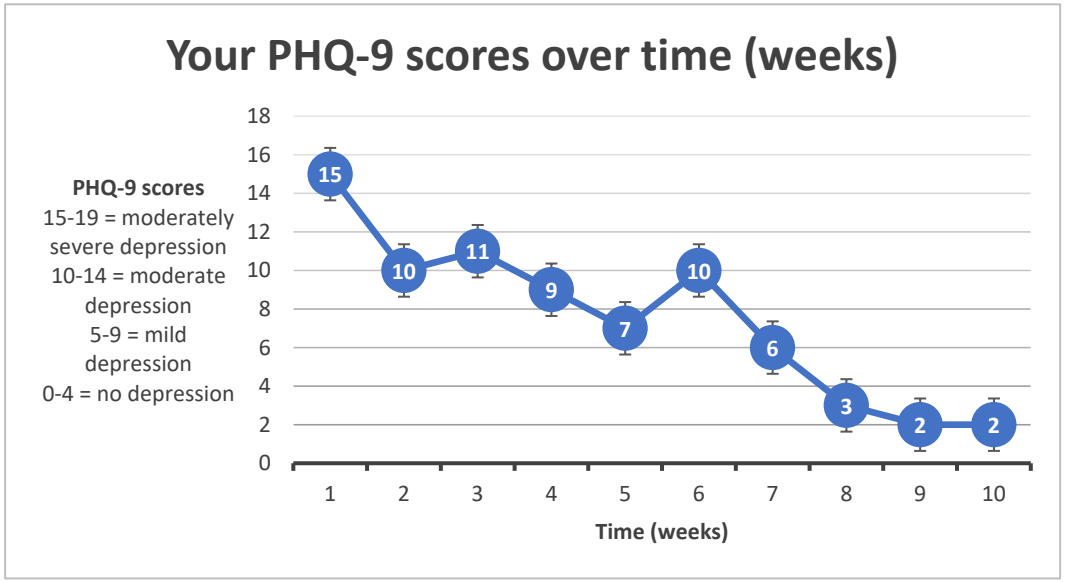
Information is provided to the user about how the tool works that is understandable for intended users

This tool presents your PHQ-9 scores calculated every 2 weeks on a graph against time. If you click on one of the entries, you will be able to review your PHQ-9 answers for that week.

The tool is presented to the user in a manner that makes it easily verifiable

User can easily review:

- Clearly labelled graph with x and y axis titles and units, labelled directionality and key as shown in the graph below;
- Previous scores and answers to verify as per example 11.



Interpretation: Line going down means fewer symptoms and/or symptoms are less severe.

User is signposted for more information

If user has any questions or concerns regarding the result, they are advised to contact a healthcare professional.

User studies have been undertaken and provide evidence that the tool is easily verifiable

User studies has been undertaken and provide evidence that a typical user understands the information and can reliably detect whether a score is incorrect and check it, without additional aids such as a calculator, and is therefore easily verifiable for a typical user.

7. Accessories, multi-modular and inter-connected DMHTs

DMHTs can be made up of various software **modules** where some qualify as SaMD and others do not. Manufacturers can choose to regulate the DMHT modules that qualify as SaMD as **separate products** or all the modules as **one product**.

A DMHT that qualifies as SaMD may need (non-medical or medical) hardware devices in order to work. If this is not specific, for instance, any off-the-shelf mobile, laptop, virtual reality (VR) headset, and the DMHT is placed on the market separately with the IFU noting the general required devices, then the DMHT can be regulated as **standalone SaMD**.

However, if the DMHT that qualifies as SaMD which needs a specific hardware device, for instance, a specific brand of VR headset, and this is placed on the market for this intended purpose, the DMHT or hardware may be considered **components of one medical device**, **accessories to each other** or a **system**.

If a DMHT is the **only** way of interacting with a hardware medical device, it generally is considered a **component** of the medical device.

EU MEDDEV 2.1/1 Definitions of 'medical devices', ' accessory' and ' manufacturer' and EU MDCG 2019-11 Rev 1 Guidance on qualification and classification of software in regulation (EU) 2017/745 - MDR and IVDR (2019) give definitions of an accessory. The definition of '**accessory**' requires that the accessory is specifically intended by the manufacturer of the accessory to be used together with a device. The intended use of the accessory must be such as to enable a device to be used in accordance with its intended use. Therefore, a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices.

A **system** could be a combination of laptop (not a medical device), software (a medical device) and transcranial direct current stimulation device (a medical device) if these are placed on the market together.

Irrespective of how a manufacturer chooses to regulate their multi-modular or inter-connected product, they should always have evidence that the software modules and hardware combination is safe and performs as intended.

8. Determining regulatory classification

If a DMHT qualifies as SaMD, the regulatory classification needs to be determined. The regulatory classification rules are different for the UK MDR, EU MDD and EU MDR and the following sections outline the detail of each. The legal text for classification of SaMD in the new UK framework is still being developed.

The choice of whether to follow the EU MDD, EU MDR or new UK framework depends on where and when the DMHT will be placed on the market (For more information, please see section title 'Application of this guidance' and MHRA guidance on regulating medical devices in the UK (2022)). In the context of SaMD, it is also important to note that currently many of the app stores have a category for UK but do not separate the market into GB and NI, therefore if you plan to place your device on the market via these app stores, your medical device needs to be compliant with both GB and NI regulations.

8.1. UK MDR & EU MDD classification rules for DMHTs

In EU MEDDEV 2.1/6 Qualification and classification of stand lone software (2016) and MHRA SaMD guidance, the following UK MDR and EU MDD classification rules are most applicable for DMHTs:

Implementing rule 2.3
Software, which drives a device or influences the use of a device automatically falls into the classification of that device.

Rule 9
All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.
All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

Rule 10
Active devices intended for diagnosis are in Class IIa:
- if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
- if they are intended to image in vivo distribution of radiopharmaceuticals,

- if they are intended to allow **direct diagnosis** or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 12
All other active devices are class I

In the MHRA SaMD guidance, further guidance on direct diagnosis states:

A device is considered to 'allow direct diagnosis' when:

- it provides the diagnosis of the disease or condition by itself,
- it provides decisive information for making a diagnosis, or
- claims are made that it can perform as, or support the function of, a clinician in performing diagnostic tasks.

For devices intended to be used by lay users, provision of an indicative diagnosis may be enough to imply that the device is allowing direct diagnosis.

It is important to emphasise here that DMHTs that provide the probability of mental health conditions or probability of symptoms highly correlated to mental health conditions, where there is a reliance on this to determine clinical management options, may be considered as providing decisive information. As such, they would be considered as providing a '**direct diagnosis**' as per rule 10 of the EU MDD and should be regulated as a class IIa medical device.

Example 14 – DMHT that provides **probability** of mental health conditions and **decisive information**
A DMHT that collects information about patients and uses complex algorithms / AI to summarise this information and report probabilities of mental health conditions. Healthcare professionals rely on this output as decisive information for making indicative diagnoses and clinical management decisions, including triaging and allocating treatment pathways. This DMHT reduces the amount of healthcare professional – patient contact time needed for undertaking assessments. Evidence shows that using this DMHT helps healthcare

professionals make more accurate assessments so there are a reduced number of patients that need to change their treatment plan and therefore quicker recovery rates.

If a manufacturer of this type of DMHT does not think the outputs are being relied on as decisive information, they need to obtain evidence to show this before placing on the market as a class I and would need to monitor the use of the DMHT as part post-market surveillance to ensure that it continues to be used in a manner where it is not being used as decisive information. They may also find it helpful to design technical solutions within the product to show this. For example, the DMHT may require the user to note other decisive information used and flag when the healthcare professional has gone against the DMHT output due to this other decisive information.

8.2. EU MDR classification rules for DMHTs

In EU MDCG 2019-11 Rev 1 Guidance on qualification and classification of software in regulation (EU) 2017/745 - MDR and IVDR (2019), the following EU MDR classification rules are most applicable for DMHTs:

Implementing rule 3.3
Software, which drives or influences the use of a device, shall fall within the same class as the device. If software is independent of any other device, it shall be classified in its own right.

Implementing rule 3.5
If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in higher classification will apply.

Rule 9
All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:
— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
— if they are intended to image in vivo distribution of radiopharmaceuticals; or
— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

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.

Rule 22

Active therapeutic devices with an integrated or incorporated diagnostic function which

significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

It is important to emphasise that the wording ‘intended to provide information which is used to take decisions with diagnosis or therapeutic purposes’ is generally applicable to all DMHT that qualify as SaMD therefore almost all DMHT that qualify as SaMD will be at least class IIa as per the EU MDR.

Appendix 1 - MHRA DMHT characterisation form

Please review the following before completing this form:
IMDRF Medical Device Software: Considerations for Device and Risk Characterization
MHRA guidance on creating an intended use statement
MHRA guidance on digital mental health technology – device characterisation, regulatory qualification and classification

Section 1 – Basic details

1.1. What is the name of the DMHT?	
1.2. What versions of the DMHT are available in the UK? If there is more than 1 version available, please note the differences between the versions and the rationale for having multiple versions. If the DMHT is not yet available in the UK, please note whether there is a version available in other jurisdictions and the version and planned date for being available in the UK.	
1.3. Who is the manufacturer of the DMHT?	
1.4. Please provide links to websites and app stores providing information about the DMHT and a link for us to access the product as a demo.	

Section 2 – Intended purpose

2.1. What is the general clinical problem or unmet need this DMHT helps with?	
2.2. What is the DMHT's medical purpose and claims?	
2.3. What is the DMHT's targeted clinical symptom and / or condition?	
2.4. What is the DMHT's intended patient population?	
2.5. Who is the intended user?	
2.6. At what point in a healthcare pathway is the product intended to be used?	
2.7. Does the DMHT have any contra-indications? For instance, restrictions in patient population, intended users, operating environment. This may be because there is a lack of evidence to show effectiveness or safety in these situations or there is evidence is show that it is not effective or safe in these situations.	
2.8. What are the potential harms associated with this DMHT?	

Section 3 – Functionality
Use a new table for each function.

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	**What are the computational tasks?** **How does the software process the inputs to get the outputs?**	**What are the software outputs?**	**Functionality?**
Function 1 -			
	A. **Stores** data / information **without** change B. **Communicates** data / information **without** change or prioritisation C. **Processes user instruction** to show **fixed content** in a similar manner to a user choosing a chapter in a digital book, audio book or video. D. **Processes data / information** with an **easily verifiable** calculation / algorithm E. **Processes user instruction** with an **interactive** and / or **personalised** output F. **Processes data / information** with a calculation / algorithm that is **not** easily verifiable G. **Processes data / information** using **AI**	.	

Revision history

Date	Version	Main changes
2025.02.13	1.1	- Wording for Example 6 and Example 14.
2025.07.03	1.2	- Include numbering for titles. - Update to section ‘2. Development of this guidance’ to include details of stakeholder engagement. - Update to section ‘6. Determining qualification as SaMD’ to include info on when DMHT does not qualify as SaMD. - Update to section ‘6.2 Does the DMHT have sufficient functionality?’ to include background of concepts in EU and UK guidance. - Wording for function 10. - Update to ‘7. Accessories, multi-modular and inter-connected DMHTs’ for clarification. - Update to ‘8.2. EU MDR classification rules for DMHTs’ due to published EU MDCG 2019-11 Rev 1 Guidance on qualification and classification of software in regulation (EU) 2017/745 - MDR and IVDR (2019).