Guidance on Ambient Voice Technology-Enabled Products

Device qualification and classification

Version 1.0

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Contents

1. Development and purpose of this guidance

This guidance is intended to provide clarity on the qualification and classification of ambient voice technology-enabled products (AVT products) that are medical devices intended to be placed on the market or put into service in Great Britain (GB is England, Wales, and Scotland).

This guidance provides illustrative examples that are not intended as exhaustive lists. If in doubt about the device qualification of your AVT product after full consideration of this guidance, or if you have further questions about classification, you may also consider reviewing the MHRA's guidance on borderline products: classifying medical devices and risk. Enquiries can also be sent to the MHRA customer service centre (info@mhra.gov.uk), including details of the product, its intended purpose and how it works.

The MHRA continues to work to provide additional clarity on device qualification and other relevant topics through guidance to support the ecosystem as the software and AI field continues to rapidly evolve.

2. Application of this guidance

Some AVT products qualify as medical devices, so they must comply with relevant medical device regulations. This guidance explains how to determine this. It explains the qualification and classification of AVT products to ensure safe and effective products are made legally available in GB.

Some AVT products do not qualify as medical devices, and users in healthcare should carefully consider what information you may need and practices you should follow to deploy and use these products safely in healthcare environments. However, the approach to non-device products is outside the scope of this guidance. NHSE has issued guidance on the use of AI-enabled ambient scribing products in health and care settings to assist those adopting ambient scribing products in England.

In GB, UKCA certification for medical devices is based on compliance with the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR). This guidance applies to medical devices placed on the GB market. Under the terms of the Windsor Framework, EU Regulations on medical devices (2017/745) (EU MDR) apply in Northern Ireland (NI). For more information on the regulatory system for medical devices in NI, see: Regulation of medical devices in Northern Ireland - GOV.UK. Additionally, 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).

In general, MHRA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and should be viewed as recommendations, unless specific regulatory or statutory requirements are cited.

Please note that the MHRA is 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.

3. AVT products

Ambient voice technologies are AI-powered tools that automatically capture and convert spoken words into text and/or other outputs. Increasingly, AVTs are generative AI (GenAI) based, with powerful, general purpose Large Language Models underlying. AVT products may use these technologies for a variety of purposes.

In general, when intended for use in healthcare settings, many AVT products are currently designed to support clinical or patient documentation and workflows. For the purposes of this guidance, example outputs of AVTs could include draft letters, discharge summaries, and other clinical correspondence.

However, while some AVT products may be intended to remain limited in intended purpose, they are increasingly being designed with flexible underlying technology that can enable manufacturers to rapidly deploy more complex uses beyond the scope of such initial intended purposes.

As these products begin to offer additional features and means of integration into the increasingly digital healthcare ecosystem, it is important that each of a products' functionalities is considered in context of its specific intended purpose, risks, and benefits. A product that may be released on the market initially without a medical purpose may be given features and new functions over time by the manufacturer. These modifications may result in the product meeting the definition of a medical device. Manufacturers should assess the application of the device regulations with every change of their product. If a manufacturer wishes to market, or continue to market, an AVT product with a medical intended purpose, then it must comply with relevant medical device regulations.

4. Device qualification

AVT products that have an intended purpose that meets the definition of a medical device are regulated medical devices.

As reference, intended purpose is defined in the UK MDR, as reproduced below:

> **"intended purpose"** means
>
> (a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;
>
> (b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials;

In the UK MDR, medical devices are defined as any instrument, software or other article 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** or **handicap;**
- **investigation, replacement** or **modification** of the **anatomy** or of a **physiological process;**

If an AVT product is intended for one or more of the above purposes, it is a medical device in GB.

A product's intended purpose is defined by the claims in its instructions for use, labelling, and the manufacturer's promotional materials (e.g. websites and adverts). Importantly, while technology choices may be one aspect of demonstrating design intention and alignment with the product's labelled claims, a product's intended purpose is not specifically determined by the inclusion of any particular technology.

It should also be noted that general disclaimers (for example 'this product is not for diagnosis') are not acceptable to demonstrate a product is not a medical device if medical claims are made or implied elsewhere in the product labelling or associated promotional material, including those made on websites, sales presentations, or online advertisements. Warnings are the lowest level of risk reduction; in general, manufacturers should mitigate

risk, including the risk of reasonably foreseeable misuse, by design first or by introducing other protection measures before considering warnings.

It is the manufacturer's responsibility to ensure that the intended purpose of their product is clearly and consistently demonstrated to users and, as applicable, to regulators. MHRA guidance on creating an intended use statement in the context of Software as a Medical Device gives guidance on how manufacturers can define and communicate the intended purpose of a product to regulators in a consistent and useful manner.

5. Qualification of AVT products

As with all products, to qualify as a medical device, an AVT product must have an intended purpose that meets the definition of a medical device. As described in sections 3 and 4 of this guidance, AVT products may span a range of functionalities and underlying technologies, and manufacturers may have a variety of purposes for which they intend to market these products. Therefore, some AVT products meet the definition of a medical device and must comply with applicable medical device regulation, and some AVT products do not.

Use in a medical environment or context alone does not qualify a product as a medical device. As an example, software that digitally reproduces medical texts may be intended for a health professional to use as reference information, to help them use their knowledge to diagnose a disease, but the software's purpose to digitally reproduce a medical text is not considered inherently diagnostic. Such software intended solely to reproduce a paper document in digital format, regardless of that document's potential clinical utility, does not itself have a medical intended purpose and is therefore not a medical device. Further, the MHRA medical device standalone software guidance notes that when considering decision support software, such software may not be considered to be a medical device if it exists only to provide reference information to enable a healthcare professional to make a clinical decision, as they ultimately rely on their own knowledge. As another example, software that is used to summarise a meeting between clinical experts may output a summary with content that is valuable to clinical decision making, but the documentation of that meeting by the software, regardless of the documentation's clinical utility, does not inherently have a medical intended purpose.

To sufficiently understand a software's intended purpose, it is necessary to consider the intended and actual functionality of that product as part of a potentially broader clinical context or workflow. It is important to consider that software products used by healthcare professionals or in a healthcare setting, including in clinical workflows, do not all qualify as medical devices. It is equally important to consider that products meant to provide reference information or to summarise content may also be intended to provide additional

recommendations that go beyond administrative support. When such functionality is intended by the manufacturer, such a product may meet the definition of a medical device.

Furthermore, many AVT products are now GenAI based, utilising the broad capabilities offered by Large Language Models. As described previously, a product's intended purpose is not specifically determined by the inclusion of any particular technology. However, one of the significant strengths of GenAI technologies is their broad utility and ability to be rapidly and flexibly applied across a wide range of tasks. This may result in a GenAI based product sometimes performing outside the scope of its intended purpose with or without explicit user prompting (e.g. by including unintended outputs or hallucinated information). While user misuse and unintended outputs do not inherently introduce new intended purposes, manufacturers are expected to design their products to ensure systems behave consistently with their stated purpose. Similarly, when evaluating the intended use of a product, manufacturers should consider a reasonable user's practical expectations of the product based on how they have designed and presented the product.

It is also important to consider the hazards and features of any technology used in a product. For example, hallucination is a well-known behaviour of GenAI with potentially broad impact in AVT products. Therefore, as manufacturers develop GenAI-enabled products, the risks associated with known hazards, as well as reasonable foreseeable misuse, should be mitigated in alignment with the product's intended purpose. As noted previously, manufacturers should mitigate risk by design first or by introducing other protection measures before considering warnings.

Finally, manufacturers should also remain mindful of the intended purpose of their product and the potential for different regulatory requirements to apply if they add or support new features for the product and the intended purpose is changed as a result. When the product's intended purpose has changed, it may require assessment or reassessment as a medical device.

5.1 Examples to illustrate AVT products that are not medical devices

The examples below intend to provide further clarity on the qualification of AVT products. These are illustrative examples, not intended as an exhaustive list.

Example 1: Ambient scribe that is intended to **provide a transcript** of a clinical conversation between a clinician and a patient.

This AVT product is solely intended to help clinicians with the administrative task of documenting a clinical encounter. The transcript is provided for clinician review and editing or correction as needed. The product is not intended to provide clinical suggestions, recommendations, or other information beyond what was discussed during the encounter.

Because the product is solely intended to transcribe a conversation in a healthcare setting and is not intended to be used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or for any other specific medical purpose, this AVT product **does NOT have a medical purpose and is NOT a medical device.**

Example 2: Ambient scribe that is intended to **provide a summary** of a clinical conversation between a clinician and a patient.

This product is intended to help clinicians with the administrative task of documenting and summarising a clinical encounter for subsequent review. The summary is provided for clinician review and editing or correction, as needed, before it is saved to the patient's electronic health record. The product is not intended to provide clinical suggestions, recommendations, or other information beyond what was discussed during the encounter. It is solely intended to help clinicians streamline the administrative work they must complete while meeting with a patient by producing a summary of the encounter for the clinician, for their review and use.

Because the product is solely intended to summarise a conversation in a healthcare setting and is not intended to be used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or for any other specific medical purpose, this AVT product **does NOT have a medical purpose and is NOT a medical device**.

Example 3: AVT product that **formats information from transcripts/summaries of a given encounter into structured data** for a clinician to review, edit and confirm for inclusion in problems lists, current medications lists, order sets or other similar forms of documentation.

This product is intended to help clinicians with the administrative task of organising patient information, such as information gathered from a clinical encounter, and providing it as structured data for clinician review and confirmation. The output may be presented as reminders or checks for potentially missing data for the clinician to review and accept or reject, to help simplify their administrative workflow. The product is not intended to derive or recommend any new information to impact the clinician's clinical decision making.

The product is solely intended to create structured data from patient information, such as a transcript of a clinician's interactions with a patient, and present it for the clinician's review and confirmation. This AVT product, therefore, **does NOT have a medical purpose and is NOT a medical device**.

Example 4: AVT product that **suggests possible relevant clinical codes for review** based upon a generated transcript or summary of a clinical conversation between a clinician and a patient.

The product is intended to help clinicians with the administrative task of coding by matching potential clinical codes to terms or information from the conversation (e.g. the name of a condition stated during discussion) and to provide these codes for review. The product does not deduce diagnoses or codes from any implicit information during the encounter; it is suggesting codes based on explicitly mentioned clinical terms during the discussion.

The product is intended to match direct language from a clinical conversation with relevant reference information (e.g. clinical codes) for the clinician's review and use. This AVT product, therefore, **does NOT have a medical purpose and is NOT a medical device**.

Example 5: AVT product that **drafts a discharge summary or letter** for a clinician to review and edit, based on patient information from sources such as the electronic patient record or transcripts/summaries of conversations from a given encounter.

This product is intended to help clinicians with the administrative task of documenting a clinical encounter and drafting a formatted/templated summary or letter for clinician review. The draft output may also include information about the patient retrieved from their electronic patient record and take the form of discharge summaries or formatted letters for the clinician to review, edit, and use to help simplify their administrative workflow. The product is not intended to derive or recommend any new information to impact the clinician's clinical decision making.

The product is solely intended to summarise a clinician's interactions with a patient and present existing medical information about that patient in a draft format for the clinician's review and use. This AVT product, therefore, **does NOT have a medical purpose and is NOT a medical device**.

5.2 Examples to illustrate AVT products that are medical devices

Example 6: AVT product that provides a summary that includes **an option for "generated insights"** based upon a clinical conversation between a clinician and a patient. **These generated insights provide suggested diagnoses or relevant follow-up and treatment options.**

This manufacturer suggests through labelling or promotional material that the product is intended to help clinicians with the administrative task of documenting and summarising a clinical encounter for subsequent review, including disclaimers that the product is not intended to provide clinical suggestions, recommendations, or other information beyond what was discussed during the encounter. The summary is provided for clinician review and editing or correction as needed. However, the product is presented to allow users to request insights as part of the summary or re-generate a summary with insights. "Insight generation" is a feature discussed in sales material. The manufacturer has designed the insights feature to allow the inclusion of diagnoses or treatments with a warning in the product's user interface that says, "the insights feature is not intended to replace traditional methods of diagnosis or treatment."

While the manufacturer states that the product is only intended to summarise a clinician's conversation with a patient for the clinician's review, it clearly highlights features in the user interface for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. This AVT product, therefore, has **a medical purpose and is a medical device.**

Example 7: Ambient scribe that solely provides a summary of a conversation between a clinician and a patient, where **the manufacturer claims** that the product "**guides diagnosis and treatment planning and improves patient outcomes**."

This AVT product is identical in function to the ambient scribe described in Example 2. However, the manufacturer is making specific claims that the product achieves a medical purpose (e.g., guides diagnosis and treatment planning and improves patient outcomes).

While the product may only have administrative functionality, the manufacturer is marketing the product for a specific medical purpose and making specific claims for this purpose. This AVT product, therefore, is marketed with **a medical purpose and is a medical device**.

Example 8: AVT agent that operates as an ambient scribe and subsequently finalises and saves transcripts to the electronic patient record without requiring a clinician's review. The product **analyses the transcript to autonomously determine necessary follow-up tests and place the relevant orders without clinician input or confirmation**.

This product is intended to autonomously make judgements, treatment decisions and take actions that a clinical professional would otherwise take or oversee. The product is designed specifically with the intent of taking actions that would be considered diagnosing or treating a patient and, further, directly acts without required review by a clinical professional such that the product's behaviour is clearly not limited to providing recommendations or reference information.

The product is intended to summarise a clinician's conversation with a patient and aggregate existing medical information about that patient, and then to analyse that information and act upon it for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. This AVT product, therefore, **has a medical purpose and is a medical device**.

Example 9: AVT product that can draft a report from a clinician's dictation or a clinical conversation and a patient's relevant test results from their electronic patient record. The product **analyses these data and provides suggested diagnoses** as diagnostic recommendations for a clinician's review.

This product is meant to help clinicians easily produce formatted reports from their own dictation and medical information retrieved from a patient's record, which may be included in templated fields (i.e., included without further processing or transformation of the data). However, the product is then further intended to analyse these to also recommend suggested diagnoses for the report. The suggested diagnoses are generally based upon the data used for the report, but the reasoning for the diagnoses may not be presented at all or may be presented in a very limited manner (i.e., the healthcare professional is intended to rely on the output of the software without review of the reasoning for the diagnosis, rather than rely upon their own knowledge).

The product is intended for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. This AVT product **has a medical purpose and is a medical device**.

6. AVT devices and UK MDR regulatory classification

If an AVT product qualifies as a medical device, the regulatory classification needs to be determined. The regulatory classification rules are different for the UK MDR and EU MDR. This section outlines the relevant detail of the UK MDR 2002. The consequence of being classified as class IIa and above is that certification by an approved body (for UKCA) and/or a notified body (for CE) is required.

The choice of which regulatory framework to follow depends on where and when the AVT device 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)).

For the purpose of classifying general medical devices (see: Part II of the UK MDR 2002), devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42/EEC of the EU medical devices directive (EU MDD).

In the MHRA medical device standalone software guidance, the following classification rules are most applicable for AVT devices which, like other software, are active devices:

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 medical device standalone software guidance, it defines active devices for diagnosis as:

- Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

The guidance also clarifies 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.

It is further stated that, 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.

Notably, providing 'decisive information for making diagnosis' may include a potentially broad range of outputs and presentations of such outputs. For example, AVT devices that are intended to determine the probability of a patient having a disease or condition based on an analysis of a clinical interaction or other medical information, where such information is intended to be relied upon to determine treatment or 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.

Revision history

Date	Version	Main changes