Hardian Health

Innovate UK

Health Innovation Network South London

Module 2: Am I building a medical device?

Exploring the definitions and terms that define medical device software classification, as related to XR/VR mental health devices.

Outline

This module will cover:

- Medical device definition UK vs EU
- The importance of the intended use
- Software as a medical device
  - When is software a medical device
- Multiple choice questions

Medical device definition

🇬🇧 UK MDR 2002 - Medical Device Regulations currently covering Great Britain

> *"medical device" means an instrument, **apparatus, appliance,** material or other article, whether used alone or in combination, **together with any software necessary for its proper application**, which—*
>
> *(a) is intended by the manufacturer to be used for human beings for the purpose of-*
>
> *(i) **diagnosis, prevention, monitoring, treatment or alleviation of disease,***
>
> *(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
>
> *(iii) investigation, replacement or modification of the anatomy or of a physiological process, or*
>
> *(iv) control of conception; and*
>
> *(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,*
>
> *and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;*

Medical device definition

🇪🇺 EU MDR - Medical Device Regulations covering the European Union

> *'medical device' means any instrument, **apparatus, appliance, software**, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> ***— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,***
>
> *— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
>
> *— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
>
> *— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*
>
> *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

Intended Use

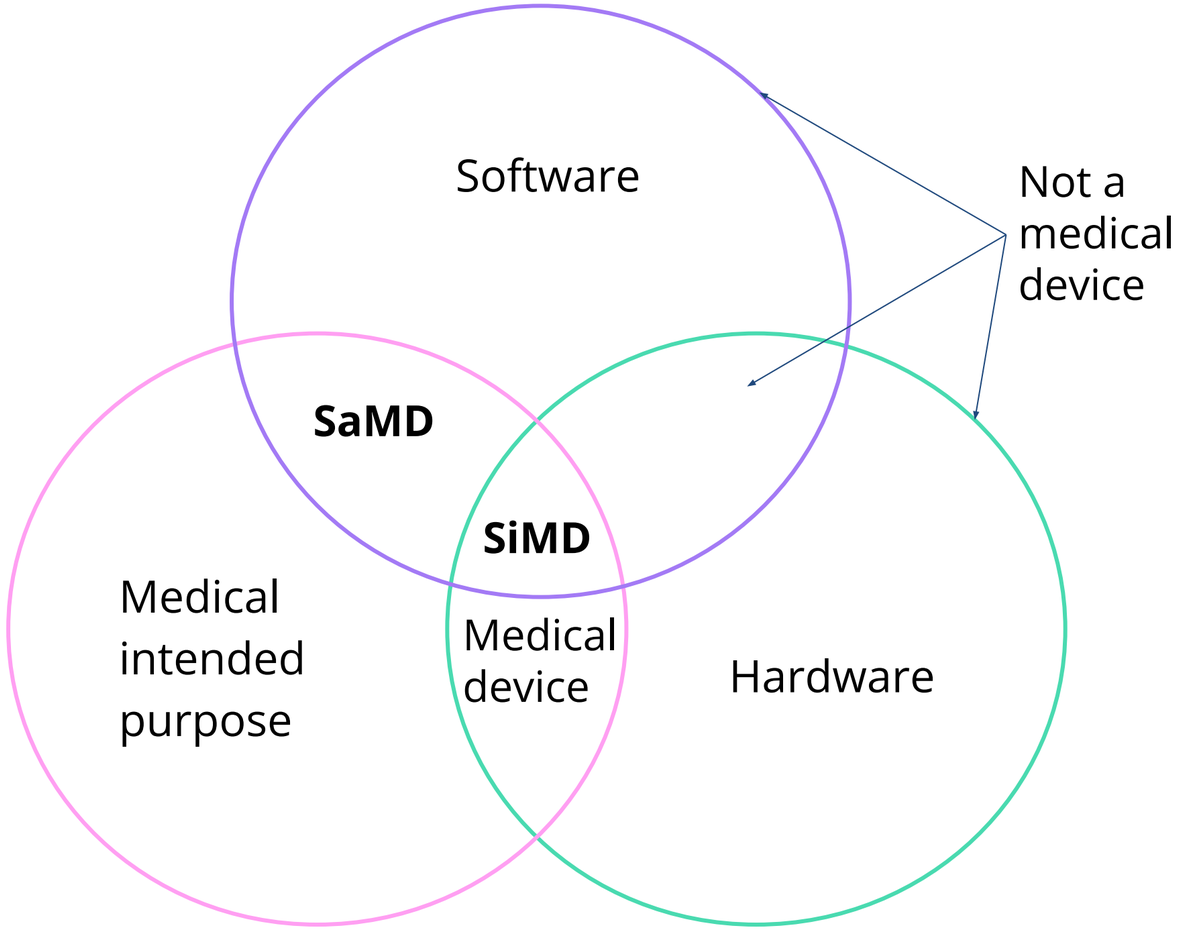
Whether or not your device is a regulated medical device comes down to the intended use.

If your device is intended to be used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease, injury or disability for individual patients it is very likely to be a medical device.

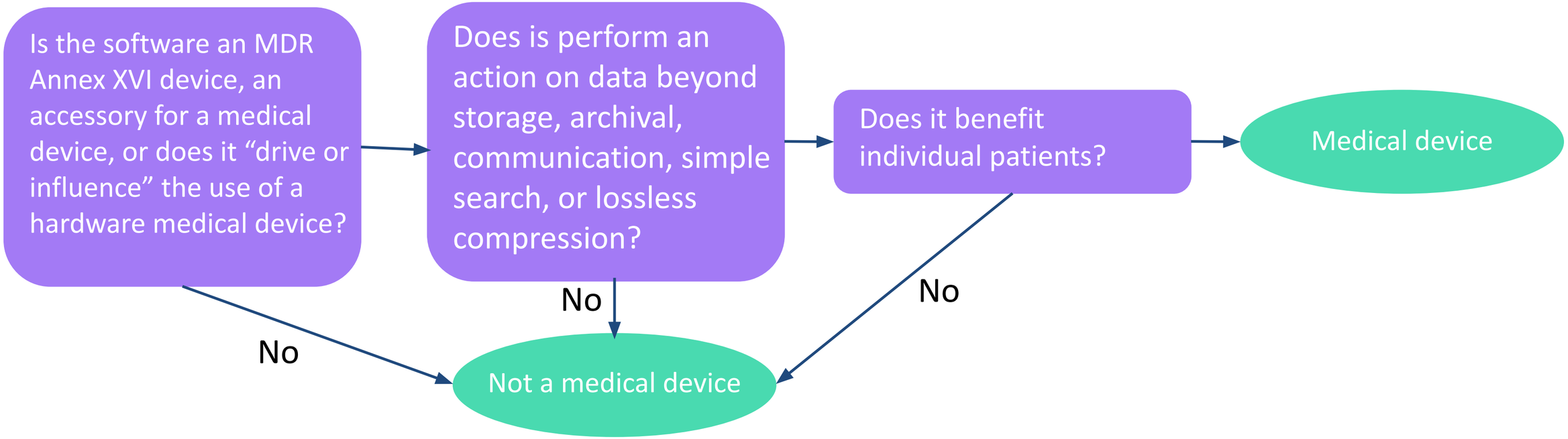
Having a clear intended use statement can help you determine the medical device status of your product.

Software as a Medical Device (SaMD)

- “Software” is considered a set of instructions that processes input data and creates output data.
- Software as a Medical Device (SaMD) also includes AI as a Medical Device (AIaMD).
- Software can also be an accessory to a medical device specifically when it enables or directly assist the medical functionality of a medical device(s) in terms of its intended purpose(s).



Is your software a medical device?



Things that can make your product a medical device

This list is not exhaustive...

- Quotes or testimonials repeated in product literature or your website.
- Any medical claims you make, including in: adverts, app store description and category, your website and social media channels.
- If a consumer would view it as a medical device.
- **General disclaimers are NOT enough.**

Non-medical device features

With a focus on software

- Not all software used within healthcare is qualified as a medical device.

- Actions such as “Simple search”, which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software (e.g. library functions).

- Software intended for non-medical purposes, such as invoicing or staff planning, does not qualify as a medical device software and does not fall under the Medical Devices Regulations.

Summary

The exact definition of a medical device varies by jurisdiction, so check the relevant regulations.

Intended use, intended use, intended use.

Be clear and consistent with your claims. Anything you claim has to have evidence to back it up!

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