Medicines & Healthcare products Regulatory Agency

Ask for regulatory advice for medical devices

Use this form to request a regulatory advice meeting for medical devices or in vitro diagnostic devices. Please note that some sections of the form may be skipped, depending on the answers you provide.

* Required

About you

Organisation name *

Contact address *

Contact name *

Telephone number *

Contact email address *

About the product

Does the advice sought relate to a product(s)? *

- ◯ Yes
- ◯ No

What UK regions are relevant to this device? *

- ◯ Great Britain
- ◯ Northern Ireland
- ◯ Great Britain and Northern Ireland
- ◯ Don’t know

What is the market stage? *

- ◯ Pre-market
- ◯ Post-market
- ◯ Don’t know
- ◯ Other

If you selected "other" to the previous question, please specify *

Intended use(s) *
Including proposed intended use(s)

What are the indications for use? *

What is the device's intended patient population? *

Who are the intended users? *

At what point in a healthcare pathway is the product intended to be used? *

What are the device's warnings, precautions, and residual risks? 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.

What are the potential harms and/or risks associated with this device(s)? *

What is the level of risk posed by the device? *

- ◯ Low individual risk and low public health risk
- ◯ Moderate individual risk and low public health risk
- ◯ High individual risk and/or moderate public health risk
- ◯ High individual risk and/or high public health risk
- ◯ Don't know

GMDN code

Including proposed GMDN code. If you do not know the GMDN code, please leave this blank.

Type of product *

Click all that apply

- ☐ Active implantable medical device (AIMD)
- ☐ General medical device (excluding AIMD)
- ☐ In vitro diagnostic (IVD) device
- ☐ Software/AI as a medical device
- ☐ Custom made device
- ☐ Procedure pack
- ☐ Other

If you selected "other" to the previous question, please specify

Is this product currently under assessment in any other jurisdiction? *

If yes, please specify

Has advice been sought from the MHRA Innovation Office on this development programme? *

- ◯ Yes
- ◯ No

Please provide the Innovation Office reference number (if known)

If you do not know your reference number, please leave this blank

Is your product software/AI as a medical device? *

If yes, we will ask some software/AI specific questions

- ◯ Yes
- ◯ No

What type of software is your device? *

Select all that apply

- ☐ Generative AI
- ☐ Language model AI
- ☐ Medical device machine learning AI
- ☐ App
- ☐ Website
- ☐ Programme
- ☐ Mathematical model
- ☐ Firmware
- ☐ Active device/hardware
- ☐ Other

If you selected "other" to the previous question, please specify

Please provide links to websites and app stores providing information about the device and a link for us to access the product as a demo.

What are you requesting regulatory advice for?

Relevant background information *

Please provide any background information necessary to understand your questions. This could be background information on the product (if applicable).

If you are requesting advice for software/AI as a medical device, please describe any functionalities not covered in the previous sections. Please describe the data inputs, computational tasks, how the software processes the inputs to get the outputs, the outputs, and any calculations/algorithms.

List of questions *

Please provide a list of questions you would like advice on.

Your preferences for a meeting

Preferred meeting date(s) *

Unavailable meeting date(s) *

Declaration

I understand that information on this form will be held on a secure, digital platform for access by the MHRA. By checking this box, I consent to the information submitted being used as described above. *