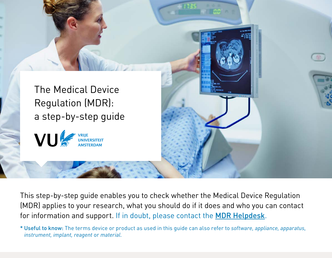

The Medical Device Regulation (MDR): a step-by-step guide

VU VRIJE UNIVERSITEIT AMSTERDAM

This step-by-step guide enables you to check whether the Medical Device Regulation (MDR) applies to your research, what you should do if it does and who you can contact for information and support. If in doubt, please contact the MDR Helpdesk.

* Useful to know: The terms *device* or *product* as used in this guide can also refer to *software, appliance, apparatus, instrument, implant, reagent or material*.

1A

Do you conduct research with or into the use of a *medical device*?

Yes? -> Go to question 2 | No? -> Go to question 1B

A device* is categorised as a medical device if it meets one of the following criteria:

- **The device serves a medical purpose.** In other words, it is intended for:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease or illness,
  - 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.
- **You are using the device within the context of research or an investigation with a medical purpose.** See also previous point. In some cases, the device itself may not have a specific medical purpose, but it can nevertheless be used for such a purpose.

Examples
You are developing software to control a VR headset to help people with Parkinson's disease combat the sensation that their feet are 'stuck to the ground' (freezing of gait). In that case, your software is categorised as a medical device.

A wearable fitness tracker is categorised as a medical device in certain situations, for example, if you use it as part of a project to help people with obesity lose weight. But if you use the tracker to only measure heart rate, for example, in order to gain a better understanding of stress, it is not regarded as a medical device.

- **Your device is still at the development stage and the goal is to use it as a medical device at a later stage.** For example, you might test a prototype on subjects to validate the device or certain parts of it. Although the prototype may not yet fully meet its intended medical purpose, it is already categorised as a medical device. If your only aim is to demonstrate the mechanism of action for academic purposes, then it is not regarded as a medical device.
- **The manufacturer states that the intended use serves a medical purpose.** Check this in the manual, the instructions for use, the investigator's brochure, the technical file or ask the manufacturer.
- **The device has a valid CE marking as a medical device.**
  - Examine the CE certificate.
  - Or check the manual, the user guide or ask the manufacturer.

Is this software categorised as a medical device?
If you have any questions, please contact the MDR Helpdesk.

1B

Does your device belong to a product group that is governed by the medical device regulations since 26 May 2021?

Yes? -> Go to question 2

No? -> Then the MDR does not apply to you. Good luck with your investigation/research!

The following product groups are covered by the Medical Device Regulation (also known as MDR Annex XVI) since 26 May 2021:

Although these products serve no medical purpose, they are still covered by the MDR. In most cases, they are devices for aesthetic or cosmetic use (e.g. contact lenses, dermal fillers and equipment used in liposuction or hair removal). These devices carry a similar safety risk as the alternative medical device and are therefore governed by the MDR.

- Contact lenses or other items intended to be introduced into or onto the eye.
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts, **with the exception of** tattooing products and piercings.
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction (e.g. Botox), **excluding** hair fattening.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for lipolysis or liposuction.
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
- Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

I'm not sure whether this is a medical device.
If you have any questions, please contact the MDR Helpdesk.

2

Are you using the medical device according to the MDR definition of 'clinical investigation'?

Yes? -> Go to question 3

No? -> Then the MDR does not apply to you. Good luck with your research/investigation!

Definition of clinical investigation according to the MDR

Any systematic investigation involving one or more human subjects, undertaken to assess **the safety or performance** of the *medical device itself*.

Examples
To obtain high-resolution images of lung diseases, a new pulmonary catheter is being developed. This is inserted into a patient's lungs using a bronchoscope. You are conducting an investigation to assess the safety of the pulmonary catheter. According to the criteria used in the MDR, this constitutes a clinical investigation.

You are using a body thermometer – generally classified as a medical device – to investigate the links between body temperature and depression. Your investigation is not focused on the medical device itself. According to the criteria used in the MDR, this does not constitute a clinical investigation.

3

Does the device have a CE marking as a medical device?

Yes? -> Go to question 4 | No? -> Go to question 5

- Check the CE certificate to see if the product is certified as a medical device.
- Or check the manual, the user guide or ask the manufacturer.

4

Are you using the medical device in exact accordance with the medical purpose described by the manufacturer?

Yes? -> Go to question 6 | No? -> Go to question 5

5

Do you want to obtain a certificate and CE marking so that you can market the device?

Yes? -> Go to question 11 | No? -> Go to question 9

- In addition to the MDR Helpdesk, you should also contact IXA VU.
- Tip: To develop a prototype, you can also contact the Electronics workshop or the Fine Mechanics and Instrumentation workshop at the Faculty of Science or at the Faculty of Behavioural and Movement Sciences.
- Then go to question 11.

What does IXA VU do?

Innovation Exchange Amsterdam VU (IXA VU) is the knowledge transfer office of VU, specialising in valorisation. IXA VU supports researchers in developing their innovative ideas into competitive products and services. For example, if you would like to enter into a partnership with a company or foundation, or set up a company.

IXA VU can inform and advise you on the follow-up steps you need to take to obtain or extend your CE marking. For example, they can put you in contact with an industrial. This partner can then help you arrange the necessary documentation.

6

Is your research or investigation part of a Post-Market Clinical Follow-Up (PMCF)?

Yes? -> Go to question 7 | No? -> Go to question 8

Post-Market Clinical Follow-Up (PMCF):

Clinical investigation which you conduct to further assess a device which already bears a CE marking. This entails a continuous process of clinical evaluation during the phase of bringing a medical device to market.

7

Do you submit subjects to *additional, invasive* or *burdensome procedures* in addition to the standard treatment?

Yes? -> Go to question 10

No? -> Then the MDR does not apply to you. Good luck with your investigation/research!

Additional, invasive and *burdensome* procedures are defined as follows:

- **Additional procedures:** Procedures additional to those which you perform under the normal conditions of use of the medical device.
- **Invasive:** Investigation whereby the device, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. For example, a blood test.
- **Burdensome:** An investigation that requires effort from the human subject and/or may cause stress. For example, an additional EEG examination in which electrodes are placed to measure brain activity.

Is my research/investigation regarded as 'burdensome'?
If you have any questions, please contact the MDR Helpdesk.

8

Are subjects required to undergo a procedure or perform an action and/or comply with certain behavioural rules?

Yes? -> Then the Medical Research (Human Subjects) Act (WMO) applies. Go to question 9

No? -> Then the MDR and WMO do not apply to you. Good luck with your investigation/research!

Medical Research (Human Subjects) Act (WMO)

The Act is relevant to this question. An investigation or research is only governed by the Act if it affects the physical and/or psychological integrity of the subject. First and foremost, the subject must be directly involved in the research. In other words, retrospective investigation or research – whereby the subject does not have to do or refrain from doing anything – is not governed by the Act.

Examples
The subject is given a list of personal questions about aspects of their life (e.g. sexuality, health). This may result in stress, which means that the subject's psychological integrity is compromised. In such cases, the Act does apply.

Taking a blood sample from a subject is also governed by the Act, as the subject's physical integrity is affected.

There are also some grey areas in this regard. An investigation that requires a participant to provide a urine sample only once is not usually governed by the Act. But if the participant has to provide urine samples over a three-week period, then the investigation is covered by the Act.

Are you in doubt as to whether your investigation or research is covered by the Medical Research (Human Subjects) Act (WMO)? Contact the Medical Ethics Review Committee (METC) of Amsterdam UMC. If your investigation or research turns out not to be covered by the Act, the Committee can issue you with a non-WMO statement.

9

Contact the MDR helpdesk

- Contact the MDR Helpdesk. Among other things, the Helpdesk can put you in touch with the Electronics workshop or the Fine Mechanics and Instrumentation workshop at the Faculty of Science or at the Faculty of Behavioural and Movement Sciences to facilitate the development of your medical device.
- Once you have done this, check whether the options given in question 11 apply to you.

The MDR Helpdesk will help you take a structured approach to compiling an investigator's brochure. This includes the safety tests you carry out, the design of the medical device, a risk analysis, considering how the device should be used, user literature survey and so on. For this purpose, the Helpdesk will supply you with a set of documents accompanied by a verbal explanation.

The brochure includes the Investigational Medical Device Dossier (IMDD), Participant Information Form (PIF), patient consent statements and the Clinical Investigation Plan (CIP). You then submit the brochure to the Medical Ethics Review Committee (METC). Check question 11 to see whether you also have to submit the brochure to the Central Committee on Research Involving Human Subjects.

10

Contact us

- Contact both the MDR Helpdesk and IXA VU.
- Then go to question 11.

11

Does your investigation or research involve one of the following situations?

Yes?

- Submit the investigator's brochure through EUDAMED and to the Central Committee on Research Involving Human Subjects.
- Once you have submitted the brochure, you have completed all the steps. Good luck with your investigation/research.

No?

You only need to submit the investigator's brochure to the Medical Ethics Review Committee (METC). Good luck with your investigation/research!

In the following situations, you are also required to submit your file to the Central Committee on Research Involving Human Subjects:

- **You want to obtain or extend a CE marking so that you can market the device.**
- **Your investigation or research is governed by the Central Review of Medical Research Involving Human Subjects Decree (BCRI) if:**
  - it concerns a clinical investigation or research involving pregnant women or mothers who are breastfeeding;
  - it involves living human or animal cells;
  - it involves genetically modified organisms or human embryos.

Good luck with your research!