OPEN SOURCE MEDICAL DEVICES

A VISUAL GUIDE FOR MAKERS

An introduction to the regulations to design, commercialize and distribute an open source medical device in EU

STEP ONE — UNDERSTAND WHAT YOU ARE RELEASING

Are you developing a hardware device or a digital fabricated solution to solve a challenge in the field of health and care? Not all the solutions need to be certified as medical devices. Identify which scenario your solution belongs to.

SCENARIO A

Your solution is a functioning DIY prototype. People can access the documentation to potentially produce and use it for themselves, to test, improve or study it.

SCENARIO B

Your solution can be personalized and produced in a fablab or a makerspace to support real people's needs.

SCENARIO C

Your solution is a hack of an existing object or medical device.

SCENARIO D

You are self-producing a solution for one person, or a few people, who will get it directly from you to use it in their daily life.

SCENARIO E

Your solution can be potentially mass produced or manufactured in small scale,and distributed by a third party, like a non profit organization, a tech for good company or by your future social enterprise.

YOU PROJECT NEEDS THE CERTIFICATION !

WHAT SHOULD YOU DO?

Document the solution clearly and do not forget to add some information regarding what it should be improved to make it more stable.

SEE EXAMPLES ON CAREABLES.ORG

Do not forget to add information about the safety and the results of testing sessions into the documentation. Make people aware about possible risks when using the solution.

Make people aware that the hacked version of a medical device is not suitable for all.

SEE INITIATIVE HACKABILITY.IT

You are responsible for your designs. Reflect on how to avoid risks for the people.

Be sure that the requirements for the EU regulation compliance are considered in the design and development process of your solution.

GO TO STEP TWO

STEP TWO — UNDERSTAND THE MEDICAL PURPOSE

To start the certification procedure you should identify what category your medical device belongs to. Look at the following medical purposes to work out what type of medical device you are working with.

TYPE	PREVENTION	DIAGNOSIS	MONITORING	PREDICTION	TREATMENT	COMPENSATION FOR	PROVIDING INFO WITH ANALYSIS
DEFINITION	The act of stopping something from happening.	A judgment about what a particular illness or problem is, made after examination.	To watch and check a situation carefully for a period of time in order to discover something.	A statement about what it will or might happen in the future.	Medical care given to a patient for an illness or injury.	To make something bad less severe, such as pain or problems.	In vitro analysis of specimens derived from the human body
EXAMPLE	Device for breast self-examination	Low cost echo-stethoscope	Intelligent monitoring device for Parkinsons	Low cost sensors for early disease detection	Pad for growing bacteria and cure vaginal infections	DIY stoma bag	Open source machine (PCR) to make copies of DNA segments

STEP THREE — IDENTIFY THE CLASS OF RISK

Medical devices are rated by their potential risk of use. The EU has 22 rules which will allow you to classify your project in the official Classes of Risks. Most maker projects are low risk. Explore the rules to work out what Class of Risk your project fits into.

RULES	CLASS OF RISK
NON INVASIVE (Rule 1-4)	CLASS I Low risk
INVASIVE (Rule 5)	CLASS IIA Moderate Risk
ACTIVE (Rule 9-13)	CLASS IIB Medium to High Risk
SPECIAL (Rule 14-22)	CLASS III High risk

EXAMPLE

YOUR PROJECT IS A SPORT WHEELCHAIR

It is not invasive because it does not touch orifices or emit radiations.

It is not invasive because it touches only intact skin.

It is not active because it is not electrified.

YOU PROJECT BELONGS TO CLASS I

Use the free Decision tree on UBORA platform to identify the Risk Class of your Medical Device: https://platform.ubora-biomedical.org

STEP FOUR — DETERMINE THE ASSESSMENT PROCEDURE

Medical device manufacturers have to follow conformity assessment procedures before placing products on the market. The type of conformity assessment procedure depends on the Class of Risk your project fits into.

ANY RISK FOUND?

If your device belongs to Class of Risk II or III, a Notifying Body must inspect and control your device.

If your device is low-risk and classified in CLASS I you can start a self-assessment procedure and check the compliance with the general safety requirements and harmonised standards.

Read all §3 Requirements on Annex I at this lin bit.ly/EURegulationsMedicalDevices

LET'S DO AN EXERCISE TO ASSESS THE GENERAL SAFETY AND QUALITY OF YOUR DEVICE

RISK MANAGEMENT

Are you aware of all risks that your device can cause! Can you anticipate them? Can you find a solution to them?

DESIGN AND MANUFACTURE

What materials are you using? Are they potentially harmful? What are the physical properties of your device? Is it stable enough?

INFORMATION

Does your device need instructions to be used! Is all information stated clearly?

WHAT IF — YOU DEVELOPED A CUSTOM MEDICAL DEVICE

A custom medical device is a device that is prescribed by a doctor to a patient. If you made a custom orthosis with a 3D printer that fits one person's need, this does not mean that your orthosis is a custom medical device according to the EU regulations.

"Custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs." MDR 2017/745 Article 2 (3)

ARE YOU HACKING?

A hacked version of an existing device is not a custom device.
See Scenario 3 In STEP ONE

EXAMPLES

A doctor uses your lab and equipment to commission a custom insole. You are making a custom medical device Class I, but you do not need a certification.

Open Bionics prosthetics hand

You made a custom 3D printed hand that is attached to a support.
You need to certify only the universal support.

Universal Socket Prosthetic

A doctor uses your lab and equipment to commission a custom insole. You are making a custom medical device Class I, but you do not need a certification.

Gyrobot Limited 3D printed insole

WHAT IF — YOU DEVELOPED A SOFTWARE

Software with a medical purpose can also be considered a medical device and belong to different Classes of Risks. Discover your options.

Your software connects to a medical device

Your software allows the user to read and visualise data from a glucose sensor through the sensor's official APIs.

YOU DON'T NEED THE CERTIFICATION

Glimp is an app to remotely share glycemia data from certified sensors and does not need a certification.

Your software is standalone and works as a medical device

Your software suggests a therapy according to the level of insulin. It means that the software is suggesting a cure and it is then a medical software.

YOU NEED THE CERTIFICATION !

See the regulations for classifying the standalone software mdr 2017/745, Chapter I, Article 2 (4)

CREDITS AND RESOURCES

This guide is based on the webinar Open Source Medical Device held by Carmelo De Maria and Licia di Pietro on 6th February 2019 within the series Digital Social Innovation webinars by WeMake - DSIScale/DSI4EU.

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www.wemake.cc

www.digitalsocial.eu

ubora-biomedical.org

LIST OF PROJECTS AND REFERENCES

- Careables Open Source Hardware in health care *www.careables.com*
- Hackability Methodological hackathon to co-design supports *www.hackability.it*
- Palpreast Wearable Device for Breast Self- Examination *https://bit.ly/2QCNqGN*
- Echopen open source and low-cost echo- stethoscope *www.echopen.org*
- OneRing Intelligent Monitoring Device for Parkinsons *https://bit.ly/2XkgXYC*
- E-Health: Low Cost Sensors for Early Disease Detection *https://bit.ly/2ELP1wX*
- Insoles Generate Insoles for 3D Printing *www.gensole.com*
- Glimp App to remotely sharing glycemia data sensors *https://bit.ly/2EJLrkG* *https://bit.ly/2YXdM19*
- E-Health: Low Cost Sensors for Early Disease Detection *https://bit.ly/2ELP1wX*
- Future Flora Kit to treat and prevent vaginal infections *www.gitomasello.com/Future-Flora*
- Stomanoir Cap for stoma bags *https://bit.ly/2EL1fqp*
- Open PCR Open-source PCR Thermocycler *www.openpcr.org*
- Openbionics Open-source Robotic & Bionic Hands *www.openbionics.org*
- Toowheels Open-source sport wheelchair *www.toowheels.org*
- Universal Socket Prosthetics *www.thingiverse.com/thing:2718045*
- DSI Webinars - Learning Journey Playlist *https://bit.ly/2wrSWZF*

"Open Medical Devices - A visual guide for makers" is included in e-book "Rebelling with care" available at this link
http://wemake.cc/digitalsocial/cure-ribelli/

DIGITAL SOCIAL INNOVATION

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