careables.org

COVID19 & Open Source Hardware
Legal recommendations for Makers

[Opendot Talks]

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Introduction

COVID19 & Open Source Hardware
Context

- Ever since the spread **of COVID19,** open communities of Fablabs and makers have **been joining forces** to design or reproduce **healthcare solutions** to face everyday **challenges** brought on by the pandemic outbreak

- OSH solutions may bring **benefits** to **many individuals and professionals in need**

COVID19 & Open Source Hardware

Virtuous cases & the law

- There are **many virtuous cases** in which OSH made a **crucial contribution:** *(some examples)*

  Easybreath Decathlon mask
  'Charlotte' Valve
  Intubation box

- ...but legal questions or issues may arise

THE VERGE TECH

POLICY \ SCIENCE \ US & WORLD

Volunteers produce 3D-printed valves for life-saving coronavirus treatments

Volunteers made the valves for about $1

COVID19 & Open Source Hardware

Our objective: to give legal recommendations

Public trust towards OSH, makers and Fablabs is raising

Promoting and respecting the **highest level of safety** of healthcare solutions, and its **responsible use**

Ethics and legal requirements for makers in OSH are not easy to navigate: we are here to provide some recommendations

2

Navigating the Law.
4 Recommendations

Ethics

1. Do no harm, and be responsible

- Just like everyone else, makers have a **duty to refrain from causing harm**.

- Makers and designers should **act responsibly.** If something goes wrong, there is room to be held liable (*also according to the law)*.

Medical Device & PPE
2. Evaluate Applicability, Safety & Risks
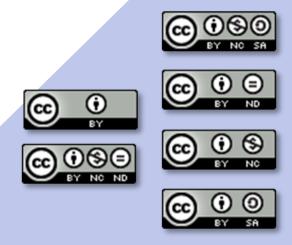

Source: Careables.org

- Some of the items to reproduce *(example:* face masks, filters, face shields) might be covered by **medical devices (MD) or personal protective equipment (PPE) laws.** Makers should check carefully if it is the case. If so, **safety requirements** must be followed.

Intellectual Property Rights
3. Keep calm and choose a license

- Makers should ensure that there will **be no intellectual property rights infringements** (*example: copyright, patent*)

- When uploading a project to a platform, makers should **decide whether and how to license it**. (note: in the absence of license, stricter copyright protection applies by default).
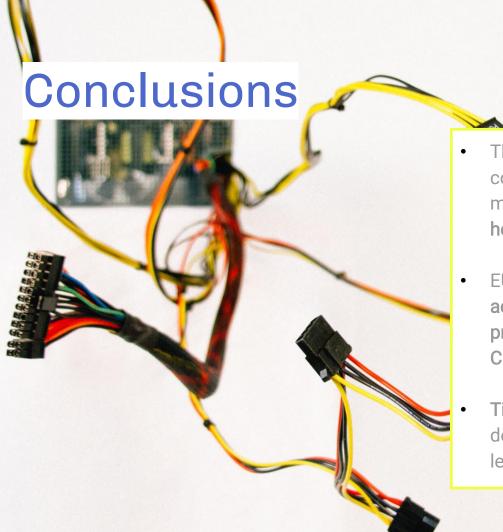
Other considerations

4. Check local laws, remember global reach

- Extraordinary circumstances may imply new exceptional rules. Makers should check new **guidance** (***example:*** *European Commission*) or **waivers** (*the Netherlands, Italy*).

- **Collaborative platforms have a global** reach: Makers should evaluate applicability of other local laws, when co-creating or replicating solutions.

3

Conclusions

Conclusions

- The number of actions of maker & designer communities have highlighted now even more the **crucial role that OSH** may have **in healthcare**

- EU and national **policy-makers are acknowledging Open Source and 3D-printing as key technologies to fight COVID19**.

- **Time for new & clear rules** for makers, designers and Fablabs at EU and national level?

Source: Randall Bruder on Unsplash

Thank you!

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Annex
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