careables.org

Deliverable 6.2
Implementation of the legal and ethical requirements

Date
June 2019

Dissemination Level
Public

Responsible Partners
KU Leuven

Editors
Erik Kamenjašević
Elisabetta Biasin

Authors
Erik Kamenjašević
Elisabetta Biasin

Careables.org is managed by the Made4You project and has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 780298.

Document History			
Version	**Date**	**Contributor**	**Comments**
0.1	April	Elisabetta Biasin	Draft ToC
0.2	April - June	Elisabetta Biasin, Erik Kamenjasevic	Input, comments
0.3	June	Erik Kamenjašević, Elisabetta Biasin	Final draft
0.4	June	Erik Kamenjašević, Elisabetta Biasin	Final draft sent for the internal review
0.5	June	Anton Vedder	Supervisor review
0.6	June	Hannan Noor	Peer Review
0.7	June	Enrico Bassi	Peer Review
1.0	June	Elisabetta Biasin, Erik Kamenjašević	Final version 1

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List of abbreviations

DIY	Do It Yourself
EC	European Commission
EU	European Union
GDPR	General Data Protection Regulation
IPRs	Intellectual Property Rights
MDD	Medical Device Directive
MDL	Medical Device Legislation
MDR	Medical Device Regulation
PDP	Privacy & Data Protection
TLT	Tort Law & Liability

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Executive summary

The Made4You project has the goal to create an online platform (Careables.org) that will function as a connecting environment for different stakeholders wishing to co-create and reproduce customised healthcare solutions ('Careables').[1] This deliverable adopts two different perspectives. The first is project-related and it aims to provide guidance: (i) for the development of Careables.org platform in line with ethical and legal requirements, and (ii) to promote the ethically and legally sound approach of the Consortium partners to the Made4You project. The second perspective is to promote the awareness for every stakeholder involved (makers, designers, caregivers, healthcare professionals, etc.) in the co-creation or reproduction of Careables with reference to the most important ethical and legal requirements. To this respect, privacy and data protection (PDP), intellectual property rights (IPR), liability and tort law (LTL), medical devices legislation (MDL), and ethics are considered to be crucial for the successful deployment of the Made4You project, the Careables.org platform, and for every single Careables project.

D6.2 has to be read in continuity with D6.1 'Legal and ethical requirement'. The document takes in legal considerations, practical guidelines and recommendations. In particular, it contains: (1) PDP guidelines to the Consortium partners for the execution of project initiatives and for the development of the Careables.org platform as well as PDP guidelines for designers and makers of Careables; (2) IPRs guidelines for the management of intellectual property rights during the development of a Careable; (3) key considerations and recommendations to explain with simple references the key concepts of tort law and liability for Careables makers and designers; (4) legal considerations on the application of MDL and the notion of manufacturer according to EU law as well as MDL guidelines on how a given item may qualify as a medical device.

The overarching objective of the document is to explain, in a plain and comprehensive manner, the key ethical and legal elements that might be relevant for the Made4You project and the Careables by providing at the same time easily understandable ethical and legal guidance. Ultimately, the document should guide the Consortium partners and open healthcare interested audiences for the execution of co-design and creation processes for open health care solutions towards an ethically and legally sound approach.

[1] Definition of a 'Careable' is currently under development by the Made4You Consortium partners. The current definition is: "an open solution that aims to improve the quality of life for people with unmet particular needs or facing physical limitations. Careables are often co-designed, replicable, accessible, adjustable and shareable online using digital technologies. Careables is a relatively new category, that promises more readily customized solutions and a more horizontal and collaborative approach to health and care".

1 Introduction

1.1 Purpose of the document

This document represents the follow-up and outcome for Task T6.1 ('Legal and ethical requirements) for the Made4You project. The goal of the task is to guide the project on the implementation of the key ethical and legal principles identified in D6.1 ('Legal and ethical inventory and in-depth analysis') and translating those in comprehensive and understandable legal guidelines. The present Deliverable is aimed at providing guidance not only to the Made4You Consortium partners for the implementation of the project but also to any stakeholder that wishes to find orientation within the ethical and legal framework of Careables. With respect to D6.1, where the ethical and legal framework relevant to the Made4You project and the Careables has been studied, this document provides a more practical approach and distils easily understandable guidelines for all the involved and interested stakeholders.[2]

1.2 Structure of the document

This deliverable is structured as to follow a pragmatic approach. Every section concerns a legal perspective worth to be analysed for the purposes of the Made4You project. First, the context and the relevance of every identified legal perspectives are described in section 2 ('Made4You methodology, programmatic approach and the ethical and legal requirements for Careables'). The subsequent sections are divided according to the legal fields that have been identified as relevant to the project, namely: **Privacy and Data Protection (PDP); Intellectual Property Rights (IPRs); Tort Law and Liability (TLT), Medical Devices Legislation (MDL).** Every section is set according to the above-mentioned domains and contains ethical and legal guidance. Section 3 ('Careables & privacy and data protection') outlines high level privacy and data protection legal guidelines for the execution of the planned initiatives of the Made4You project as well as for the development of Careables as such. Section 4 ('Careables & IPRs') provides guidelines on intellectual property rights related to Careables, input on licensing Careables, seven reasons why to consider licensing your documentation/product. These guidelines were done in order to raise awareness of the Consortium partners as well as to assist those planning to engage with Careables. Section 5 ('Careables & liability') reports on the concrete questions related to liability and tort law when it comes to the co-design and creation of open solutions by designers and makers.[3] The Section provides guidelines to makers concerning tort law and

[2] The focus of the legal analysis applied to the present deliverable is performed on an EU-level scope. Considerations for local regulations on a global scale that might result to be applicable to the Careables will have to be considered on a case by case basis.

[3] To this regard, it is worth to note that the KUL has been put in contact with Open Source Ecology Germany (OSE), "an open movement aimed at establishing an Open Source Economy optimizing both production and distribution, while at the same time promoting the regeneration of the environment and social justice", see OSE

liability paradigms that may be applicable to their field of activity as well as some remarks concerning liability and warranty clauses. Section 6 ('Careables & medical devices') addresses the question whether a Careable could be ascribed to the definition of 'medical device' and whether a subject is a 'medical device manufacturer' in the meaning of the EU MDL legal framework.

2 Made4You methodology, programmatic approach, and the ethical & legal requirements

This section explains the relevance of the legal perspectives that are being analysed (PDP, IPRs, TLT, MDL). The observations and remarks provided herein (as well as in the whole deliverable) address two different kinds of audiences. On the one hand, they concern the Consortium partners, in order to foster the ethically and legally sound approach of the Made4You project. On the other hand, observations and remarks have a wider scope, and may concern all stakeholders that get involved in the co-design and creation of the Careables.

2.1 Methodology and the programmatic approach

The mission of the Made4You project is to enable citizens to co-design and deliver people-centred healthcare solutions. Such objective may be reached through a series of actions. First, (1) by fostering the connection between existing communities of makers, engineers and fabricators with communities of individuals and healthcare professionals, on a local and global level; (2) by providing a common tool – a platform – granting all the interested individuals the access to project documentation; (3) by co-designing open healthcare solutions for individuals facing physical disablements.[4] To fulfil this mission and to reach these objectives, Made4You established the following:

- A **Methodology**: the Made4You project is founded on the key concept that, to create a solution tailored the individual needs, the end-user should be included in the development of healthcare solutions.
- A **Programmatic Approach:** the Made4You is based on four programmatic pillars, which are: 1. Pilot Open Solutions (WP2); 2. Tools & Platform (WP3); 3. Community Engagement (WP1)[5]; 4. Outreach (WP5). These pillars are formed by different components – as outlined in the Figure below.

website: https://opensourceecology.de/?ln=en. OSE provided a number of key legal questions (Working Document. Legal Issues of Open Source Hardware, May 2019) that have been analysed and substantiated in guidelines and legal considerations in Section 5.

[4] Made4You, Grant Agreement (GA), Part B, p. 5.

[5] For the purposes of the present deliverable, the term 'Community' and 'Community Engagement' are as defined and analysed in Made4You, D1.1 – 'Engagement strategy & documentation of events'.

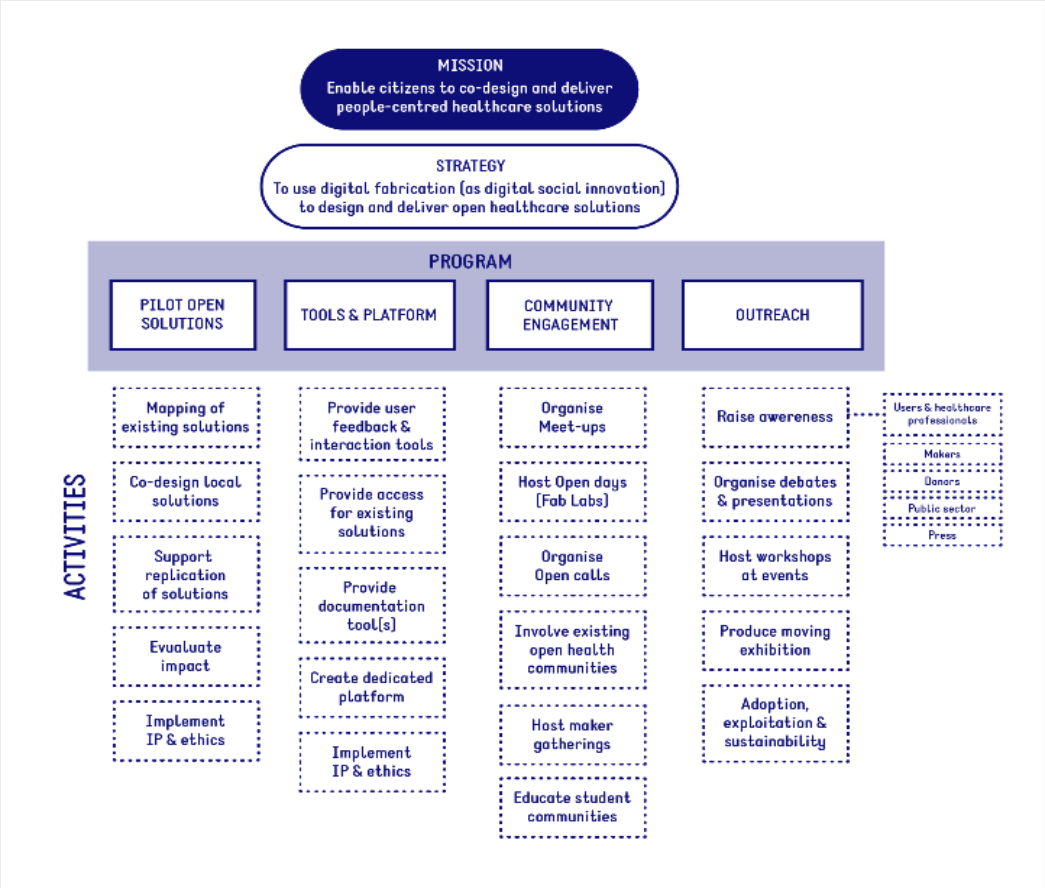

Figure 1 - Programmatic approach of Made4You

For the purposes of this deliverable, the three pillars of Community Engagement, Pilot Open Solutions, Tools & Platform and their related implementation within the project will be described in the following paragraphs. Once these practical aspects are described, the relevant legal perspectives are analysed. The latter explain the rationale for which the practical legal guidelines (contained in the subsequent chapters of the present deliverable) are provided.

2.1.1. Community Engagement

2.1.1.1. Overview

The objective of the 'Community Engagement' pillar (corresponding to the WP1 'Engagement and Community Growth') is to foster the interaction of communities of makers, engineers and fabricators, healthcare professionals and individuals in order to promote their active involvement for the co-design and development of Careables. Within the project, a series of initiatives will be carried out on a local and a global level, such as[6]: meet-ups, presentations and experience workshops on open healthcare solutions; healthcare open days for the development and prototyping of solutions with users and healthcare professionals; open calls for

[6] For a wider overview of the purposes and context of such initiatives, see also Made4You, D1.1 – 'Engagement strategy & documentation of events'.

Careable designs; maker gatherings to share knowledge on co-designing and co-developing of open healthcare solution.

2.1.1.2. Legal analysis

The legal requirements relevant to 'Community Engagement' concern **PDP:** during the above mentioned initiatives the promoters may collect and process the personal data of involved participants/stakeholders (e.g. from individuals with healthcare needs, to makers and designers, to healthcare professionals). High level guidelines on privacy and data protection are provided in 3.2.1.

2.1.2. Pilot Open Solutions

2.1.2.1. Overview

The main objective of the pillar 'Pilot Open Solutions' (WP2) is the performance, on a local dimension of **co-design sessions for Careables.** To do so, different stakeholders – designers, engineers, makers, individuals with a healthcare needs, carers, and healthcare professionals – gather together and form a multidisciplinary team. By analysing the situation and conditions of the individual with a healthcare need, the team members jointly contribute to co-creation of a Careable.

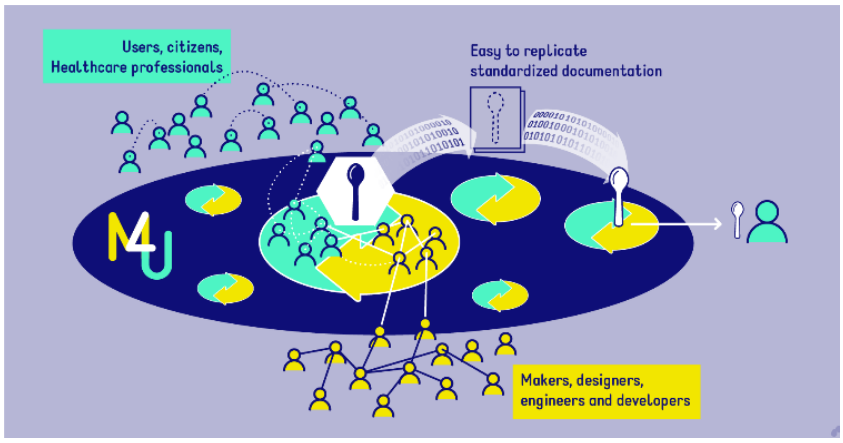

Figure 2 - Co-design of Careables

2.1.2.2. Legal analysis

The legal requirements relevant to 'Pilot Open Solutions' concern (1) **PDP:** The creative moment in which different subjects are gathered together may entail aspects related to privacy and data protection. First, the organisation of these initiatives requires the processing of participants' personal data by promoters. Furthermore, individuals' personal and sensitive data are processed in the context of such sessions (especially, data concerning health of the individual with an healthcare need) and as such particular cautions should be applied to safeguard their right to privacy.[7] Practical guidance concerning these aspects is provided under sections 3.2.1 and 3.2.3. (2) **IPRs:** Although this stage represents an early phase in which a Careable is

[7] Further ethical and legal considerations for the development of the Careable itself are provided under §2.1.4.

still in its infant shape, for those involved in the co-creation is important to start planning how will they deal with IP rights once the product is finalized. Section 4.2.1 provides guidelines and highlights the main themes that have to be considered by stakeholders involved in the Careable co-creation process. (3) **LTL:** The consequences when a Careable causes a damage to an individual may differ, depending on the nature of the Careable as well as on the kind of liability for the subjects that contributed to the creation of the Careable. Section 5.2.1 recalls the main aspects of tort and liability law with respect to the case a damage occurs to the individual using the Careable.

2.1.3. Tools and Platform

2.1.3.1. Overview

Third pillar of the Made4You project concerns 'Platform and Tooling' (WP3) which relates to the design and development of the Careables.org platform. As already described elsewhere[8], the Careables.org platform will serve as a central hub where stakeholders and communities may upload the project files, design, etc. The platform users may download the files and reproduce any item by themselves, e.g. by using fabrication tools and 3D-printers.

2.1.3.2. Legal analysis

The development and future maintenance of the Careables.org platform entails the analysis of the following perspectives: (1) **PDP**: as already outlined in D6.1, the Careables.org platform will collect and perform the processing of users' personal data. To such regard, it is of key importance that the platform is developed by following the data protection by design approach (art 25 GDPR) and in accordance with the key principles of data protection law. Guidelines concerning the lawful development and maintenance of the platform under a data protection point of view are provided in 3.2.2. (2) **IPRs**: the platform will feature mainly projects and products that are being licensed in order to foster innovation, equality, fairness and availability of healthcare tools to a broader group of individuals. Guidelines are provided in section 4. (3) **LTL**: the co-creation of prototypes and the sharing of design files within the Careables.org platform might have consequences with respect to the matter of liability and tort law. Remarks concerning licensing under a liability point of view (with respect in particular to liability and warranties clauses) are reported in 5.4.

2.2 The Careables: ethical and legal considerations

2.2.1.1. Legal & ethical analysis

Designers, makers, healthcare professionals and other stakeholders involved in prototyping of a Careable for a given individual with the specific healthcare need should always consider

[8] See GA; Made4You D1.1 – 'Engagement strategy and documentation of events; D6.1 – 'Ethical and legal inventory and in-depth analysis'.

the following ethical and legal perspectives: (1) **PDP**: privacy and data protection legal requirements, such as the data protection by design and by default principles – occurring the case a Careable performs any processing of personal data – should be regarded at by subjects involved in the Careable co-creation process. Section 3.3 is devoted to providing high level guidance to this respect. (2) **LTL**: the creation of prototypes and further use of it by an individual may have consequences for those involved in the co-design and creation process with regard to the liability and tort law. Key findings to this regard are provided in section 5.2.(3) **MDL**: while designing and co-creating a Careable, makers and designers should be able to recognise whether: (i) they should be considered as 'manufacturers', and (ii) the product falls under the definition of 'medical device'. Guidance to establish these two points is provided under section 6. (4) **Ethics**: the design of Careables should also take into account the ethical principles in order to ensure the wellbeing of individuals, society, (public) health, and the security. Ethical guidelines have been already provided in D6.1 (section 5 –'Ethical Guidelines').

3 Careables & privacy and data protection

3.1 Introduction

The execution of the Made4You project and the setup of Careables.org platform have been studied with respect to privacy and data protection legal requirements in D6.1. Particularly, the awareness on privacy and data protection legal requirements has been promoted by stressing the importance of the key notions and principles provided by the law. It has been emphasised that data protection principles (lawfulness, fairness, transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality, accountability) should be respected throughout the execution of the project and for the development of Careables.org, as well as the performance of Data Protection Impact Assessments. In continuity with the legal perspectives envisaged in D6.1, the purpose of the present section is to provide high level guidelines on privacy and data protection to the Consortium partners as well as all stakeholders that might be involved in the co-design and co-creation of a Careable.

3.2 PDP guidelines

The following sections (3.2.1 and 3.2.2) are oriented at providing practical guidance to **the Consortium partners** by paying particular attention on privacy and data protection requirements applicable to WP1 'Engagement and Community Growth', WP2 'Pilot Open solutions' as well as the implementation of measures in the context of WP3 'Platform Tooling'. In the section 3.2.3 guidelines are addressed to all Careables makers and designers.

3.2.1. PDP & Made4You project

The following table deals with guidelines applicable to Made4You Consortium partners of WP1 and WP2:

High level guidelines for organisers and promoters (e.g. Fab labs, hubs) of the initiatives within WP1 and WP2		
When	Domain	Action
Prior to the launch of the initiative	**Role evaluation**[9]	Prior to the set-up of events, organisers should **evaluate their role** in the initiative having regard to the processing of personal data they are planning to carry out or to any other processing of personal data that might take place in such context. • Where the organiser of an initiative (such as a Workshop, a Meet Up, an Open Call, etc.) defines the purposes an means (the 'why' and 'how') of the processing of personal data, it should be regarded as '**controller'**. • If the organiser is determining purposes and means jointly with other organisation(s), they should be regarded as '**joint controllers**'. • Other entities performing the processing on their behalf should be considered as '**processors'**. All individuals taking part in the initiatives, whose personal data are collected (e.g. makers in makers gathering, healthcare professionals in Experience workshops, etc.) should be considered '**data subjects**'.
	Data sharing agreements	Once controllers' role were established they should draft a **data sharing agreement** with the identified processors. This is necessary also when different entities put in place jointly the processing of personal data as **joint controllers**.
	Purpose evaluation of the processing	When defining the activities to be carried out and the scope of the initiative, promoting entities must **establish the purpose(s)** of processing of personal data.
	Legal basis	When defining the scope of the processing activity, organisers should evaluate the most appropriate **legal basis** for it.[10]
Prior and during the initiative	**Data minimisation**	Promoters should evaluate what personal data they want to collect and process in order to process only what is **strictly necessary** for the execution of the initiatives.

[9] For considerations on data protection roles see D6.1, §2.3.3.7.
[10] For guidance on data protection legal bases, see Made4You D6.1.

		The processing of irrelevant or unnecessary data should be avoided.
During the initiative	**Information**	At the moment of the data collection organisers should provide to participants an **information notice**, drafted in line with the GDPR requirements.[11]
Before, during and after the initiative	**Consent**	Promoters may ground the processing of personal data on the basis of consent of data subjects. While acquiring consent of data subjects, organisers shall ensure that is **freely given, specific, informed, unambiguous, and explicit (if sensitive data is collected)**.
		Moreover, organisers must ensure that data subjects can easily **withdraw consent** at any time.
		Organisers shall **keep track** of the obtained consent (e.g. through documentation).
	Data accuracy	Organisers shall ensure that the **data** acquired and processed is **accurate and up-to-date**.
	Data subjects rights[12]	**Data subjects should be enabled to exercise their rights** including the right to be informed, right to access, right to rectification, right to erasure, right to restrict processing, right to data portability, rights in relation to automated decision making and profiling. Organisers must evaluate and undertake all measures necessary to ensure these rights, when applicable.
	Security of processing	Organisations should be cautious in **evaluating the technical and organisational measures to ensure that all processing activities are secure**. Organisers are free to evaluate what measures to put in place (e.g. anonymization, pseudonymisation, physical measures, etc.), but they must ensure that these measures are adequate to the level of risk.
	Data breach	Organisers should **be prepared in case a data breach occurs**. It is suggested to adopt data breach policies, or to determine in advance what actions should be carried by the controllers.

[11] See D6.1, and Artt. 13-14 GDPR.
[12] For a wider overview of data subjects' rights see D6.1, §2.4.6.

	Documentation	Organisers should, where possible, **keep track** of the consent form and more generally of all the operations entailing the processing of personal data.
		The organisation's **records of data processing activities** should also report details about these initiatives.
	Data retention	Organisers/promoters must establish **data retention period** for the data that are processed within the course of these initiatives. Once the retention period has expired, organisers should define what action to put in place to ensure the proper **erasure or anonymization** of data.

3.2.2. PDP & the Careables.org platform

This section provides a list of the privacy and data protection legal guidelines that should be considered by the Consortium developers (WP3) for the design of the Careables.org platform.

High level Privacy & Data Protection Legal Guidelines for developers of the Careables.org platform		
When	Domain	Action
Prior to the design of the platform	**Role evaluation**	For the purpose of the platform, all individuals registering within the platform, as well as any individual whose image is processed within the platform (even if not registered therein), should be considered as '**data subjects**'.
	Purpose evaluation of the processing	**The purposes** of all processing activities of personal data (e.g. registration, emailing concerning specific initiatives, etc.) should be evaluated prior to the execution thereof and should be disclosed transparently to the data subject.
During the design of the platform	**Data minimisation**	The personal data to be collected and processed within the platform should only if **necessary** for the intended purposes. It is essential to evaluate this aspect during the design of the platform: any processing of non-relevant or unnecessary personal data should be avoided.
	Information	At moment of the collection of personal data, users must be provided with an **Information Notice** outlining the main aspects of the processing and drafted according to GDPR requirements.[13]
	Cookies	For the setting of cookies, a **visible notice** (e.g. a banner) that various types of cookies are being used by the website should be provided.

[13] See D6.1, and Artt. 13-14 GDPR

		In the visible banner notice, users should be entitled to agree or not to cookies being set by the websites. Users should be enabled to choose 'granularly' the cookies to be installed in their devices. There should be a mechanism by which the user can choose to accept all or some or decline cookies as well as an option for the user to subsequently change their prior preferences.
On a continuous basis	**Consent**	The processing of users' personal data within the platform may be grounded on the legal basis of consent. The acquired consent of data subjects' shall be **freely given, specific, informed, unambiguous, and explicit**.
		The platform should allow data subjects to easily **withdraw consent**. Consent must be easily withdrawn as it has been provided.
		The platform shall **keep track** of the obtained consent (e.g. logging, etc). Where possible, information on the session in which consent was expressed should be kept.
		The consent workflow at the time made by individuals should be documented.
		If the purpose of the processing changes, data subjects should be notified. If necessary, their consent should be asked for the new purpose/processing activity.
	Data accuracy	Personal data stored within the Careables.org platform should be **accurate and up-to-date**. Measures should allow to verify the accuracy of data and the records of its sources. The update or correction of personal data should be done easily.
	Data subjects rights	**Data subjects should be enabled to exercise their rights,** such as the right to be informed, right to access, right to rectification, right to erasure, right to restrict processing, right to data portability, rights in relation to automated decision making and profiling.
	Security of processing	The **processing activities** within the platform must be **secure**. To ensure this, many technical and organisational measures might be evaluated by developers (e.g. anonymization, pseudonymisation, etc.). These measures shall establish a protection to be adequate to the level of risk to the freedoms and rights of the involved data subjects.

	Data breach	Organisers should be prepared in case of a data breach occurs. A data breach policy for the purposes of internal investigation and reporting could represent an element of good practice to take into consideration for the occurrence of such a circumstance.
	Documentation	The platform should allow to **keep track** of the operations entailing the processing of personal data.
	Retention of data	Data should be stored for a period no longer than necessary for the purpose of the processing. The **retention** of personal data should be **clearly established** for the data to be processed within the platform.
In case of dismissal of the platform	**Dismissal**	It is recommended to establish policies and procedures for the eventual future dismissal of the platform, in order to ensure the proper erasure or anonymization of personal data.

3.2.3. PDP & Careables

During the co-creation process of Careables (which may occur as activity performed in the Made4You project, but also by future users of the Careable.org platform), designers and makers should consider some fundamental questions concerning the privacy and data protection.

High level Privacy & Data Protection Guidelines for Careables Designers and Makers		
When	Domain	Action
During the design of a Careable	**Data Protection by Design**	Designers and makers should question from the beginning of the project to be developed, all the relevant aspects concerning the privacy and protection of personal data of the individual that will use the Careable.
	Data minimisation	Designers should pay attention and always verify whether the Careable might collect personal data or data concerning health of an individual. For instance, data generated by devices (e.g. devices analysing a person's blood, apps measuring heart rate, etc.) might be considered health data occurring certain circumstances.[14]
	Data Protection by Default	If personal data are processed by the Careable, designers and makers should implement appropriate technical and organisational measures for ensuring that, by default, only personal data which are necessary for each specific purpose are processed.

[14] For further considerations on this regard, see also D6.1, §2.3.3.2.

	Data Protection Principles	If the Careable is designed to process personal data of a given individual, makers and designers should always pay attention to the key data protection principles (see above, §3.1).
Upload of the CAD file within the platform	**Data minimisation**	As a closing remark, it is important to evaluate, before the upload of a given CAD file in the Careabes.org platform, whether the same file contains personal data or data concerning health of an individual with an healthcare need for which the item is developed. In some cases, this information is necessary for the development of the project. When not necessary, makers or designers uploading the CAD file should put in place all the necessary measures to minimise the use of such data before the file uploading on the platform.

4 Careables & IPRs

4.1 Introduction

This section provides guidance about intellectual property rights that may arise while developing Careables. As it was shown in D6.1, two sets of IP regimes may become relevant. From the moment a Careable documentation is developed, the author/designer enjoys a copyright protection. If the designer develops a Careable that represents an inventive step and it fulfils other conditions provided by law, she/he may obtain a patent protection.

A goal of the Made4You Consortium is to encourage publishing of a complete and open documentation of Careables, i.e. a documentation that can be freely used and replicated by anyone, anytime and anywhere in the world. To be able to achieve this challenging task, it is necessary to provide guidance on how to encourage open licensing (i.e. open source, open hardware, Creative Commons).

4.2 IPRs guidelines

The following guidelines provide input about intellectual property rights and licensing options relevant for both, the Consortium partners and anyone involved in the development of a Careable.

High level IPRs guidelines for the Careables makers, developers, and users		
When	Domain	Action
During the design of a Careable	**Co-ownership**	Designers and makers developing a Careable jointly should agree on the ownership rights, exclusivity, and licensing terms.
	Copyright	Designers and makers should be aware of the copyright laws applicable to the Careable documentation, its implications, rights and duration in order to be able to adequately address and chose the licensing terms.
	Patents	Designers and makers should understand whether they fulfil the requirements to obtain a patent protection, its implications, rights, duration, limitations, fees, etc.
After the design of a Careable	**Copyright**	As soon as the Careable documentation is drafted, it enjoys the copyright protection. To meet the openness and free use goals as mentioned above, designers and makers may choose to apply one of the Creative Commons licences. *How does the licensing system work?* The application of a copyright license on a work (a Careable documentation) is possible as a subsequent phase followed by the initial acquisition of copyright protection. In other words, the author (the licensor/a person who drafted the Careable documentation) first automatically obtains the copyright for his/her work and then he/she decides on how to regulate his/her exclusive rights by applying a license on such work (the licensed work/the careable documentation) whose effects are spread on variety of indeterminate subjects (the licensees/however wants to use/replicate/etc. the Careable). Before applying a license, which will last for the full duration of the applicable copyright protection, you have to think: (1) if the material is copyrightable, (2) do you own the material you wish to license, and (3) if you are aware and agree that Creative Commons licenses are not revocable (however, you can still stop offering material under a

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		6) Attribution-Non Commercial-No Derivatives: This license is only allowing others to download your work and share it with others as long as they credit you, but they can't change it in any way or use it commercially. For further information, see https://creativecommons.org/licenses/by-nc-nd/4.0/.
	Patents	Copyright licenses cannot be applied to hardware as they are not subject to such protection but to a patent protection. If designers and makers obtain a patent protection, they may, as a second step, license the Careable under the terms they wish to apply. If they do not obtain a patent protection, designers and makers do not need to apply a license to it and everyone may be free to use the hardware freely. Here it is important to underline that copyright protection exists independently to patent protection (hence the rules described above remain applicable).

4.2.1. Why to use Creative Commons licenses?

While conducting a research and communicating with Consortium partners and the respective makers' communities, it have been concluded as follows: 1. there is a lack of awareness and practical knowledge about intellectual property rights due to its complexity, and 2. there is a lack of knowledge about the function and benefits of licensing.

In order to avoid repetition, we would like to invite everyone dealing with this question to, as a first step, have a look at D6.1. Therein, the function of IP rights and open source/hardware licensing have been extensively described. As a second step, below we provide a short description of the main reasons why to consider applying Creative Commons license to your work (in our case, on the documentation describing development of a Careable).[16]

1. Faster dissemination: distribution is decentralized since everyone using commons are empowered to share resources they have access to. Those applying Creative Commons licenses to their work "have a reduced need for sales or marketing. Decentralized distribution amplifies supply and know-how".[17]
2. Access to everyone: resources are open and provided up front without payment which promotes inclusiveness, equity and fairness.

[16] Based on Paul Stacey and Sarah Hinchliff Pearson, 'Made with Creative Commons', <https://creativecommons.org/wp-content/uploads/2017/04/made-with-cc.pdf>, 2017, pp. 13-14, accessed on 5 June 2019.
[17] Ibid., p. 13.

3. Maximized participation: everyone can participate and contribute to the licensed work either by using resources of others, contributing with your own work or mixing your work with the resources of others. This way, everyone can directly participate.
4. Encouraged innovation: the more people have access to the licensed work, the better chances are to get new ideas and innovate the used work. Consequently, research and development is shifted from one organization to the community.
5. Boosting the impact: digital commons spread the impact to by connecting creators of the licensed work with those who use and build on their work, either locally or globally. Due to that, even if your work is created for a local need it may generate a global impact.
6. Adding value to the licensed work: each use of the licensed work adds value to the work, the creator, the customer as it is more cost-effective and it produces a greater return on investment.
7. Working together for a common cause: people involved become directly responsible to manage the resources for the common good, the costs and benefits of an individual are balanced with those for the community and future generations. "By functioning on the basis of social engagement, not monetary exchange, the commons unifies people".[18]

5 Careables & liability

5.1 Introduction

This section provides guidance about tort law and liability for all involved stakeholders in the design, co-creation and reproduction of a Careable. The findings herein are based on research carried out in D6.1.[19] Plain findings concerning liability and tort law are provided under 5.2.1.1, whereas 5.2.1.2 proposes practical solutions (liability and warranty clauses) for makers based on experienced accrued in analogue research projects concerning the DIY community/environment.[20] Before outlining these key considerations and recommendations, a short debrief of stakeholders' questions on liability and tort law is delineated in section 5.1.1.

5.1.1. Open questions

Within the execution of the project and in the context of internal Consortium meeting, dissemination activities as well as in the Community Engagement phase of the project, many stakeholders have shown interest in some specific questions concerning the liability that makers/designer may have as a result of their activity. Particularly, the Open Source Ecology Germany (OSE) association provided a number of key legal questions[21] regarding liability and tort

[18] Ibid., p. 14.
[19] See Made4You D6.1, section 4.
[20] See for instance, DiDIY research project, website: http://www.didiy.eu/.
[21] OSE, Working Document. Legal Issues of Open Source Hardware, May 2019.

law that are relevant also for the Made4You project and the Careables To give an overview of the day-to-day questions that may arise within the maker community in the occasion of their activities, and with the purpose to animate the policy-making debate on this matter, an extract of the OSE questions is reported herein below:

Extract of OSE Questions concerning liability[22]
"Liability Issues *Martin develops an electric motor and publishes the technical documentation under CERN OHL 1.2 (licensor). Timm invents a wind turbine which includes this motor (licensee). He publishes the whole design under CERN OHL 1.2 (licensor), naming Martin expressly as the author of the motor. Lars builds and sells some of these wind turbines, following Timms (and Martins) published designs.* *Damage case. Several people die. Investigations show that the damage happened due to a construction failure of the motor.* 1. *Who is liable for the contractual damage (broken wind turbine) of Lars' customer?* 2. *Who is liable for the tortious damage (dead people etc.)?* 3. *May the liability be transferred to others in the chain (Lars → Timm → Martin)?* *If yes, how to reduce the risk that the author of underlying open licensed information can be made liable in a case of damage?"*[23]

5.2 TLT & Careables

The legal aspects concerning the liability issues that may arise for the co-design, development and reproduction of Careables have been analysed in D6.1 (Section 4 – 'Made4You, Careables and implications concerning Liability). As said therein, there is little legal certainty in this field of law given the innovative degree of the DIY environment practices. To provide a clearer overview of TLT legal takeaways for the Made4You Consortium partners and the Careables stakeholders, key considerations and recommendations are provided below.

5.2.1. TLT key considerations and recommendations

5.2.1.1. Key considerations: tort law and liability

TLT Key considerations for stakeholders involved in Careables co-design and co-creation
• In the frame of the Careables co-design, creation and manufacturing, **there is a wide range of players** (designers, makers, healthcare professionals – in case of 3D reproduction of the Careable, the owner of the printer, the manufacturer/supplier of the printer). The interplay of these subjects may lead to potentially overlapping liability responsibilities.

[22] Ibid.
[23] Ibid.

- The frame of Careables co-creation and manufacturing requires also to take into consideration the **variety of different regulatory frameworks** that might be applicable (to name a few, product liability laws, civil liability laws, medical devices laws, intellectual property laws).[24]
- When a product is defective and causes personal injury, product liability law foresees the producer to be strictly liable. Hence, product liability law foresees as standard rule the application of the **strict liability doctrine**[25] for producers. Such doctrine sees **the manufacturer liable if the product is defective**, even if there is not the negligence of the manufacturer in making that product defective.
- **Strict liability applies to products which have been industrially produced**. Producers may not be held liable (in the sense and for the effects outlined by the Product Liability Directive) if they prove "that the product was neither manufactured […] for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business"[26]. This **exception on strict liability** might be applicable to DIY environment but there is no specific case law available on this issue. Hence, a **case-by-case approach** should be adopted. Strict liability rules could be applied when an entity is a regular seller, rather than an occasional or casual one.
- **In Europe, civil liability is a not a harmonised matter**, meaning that every Member State regulates civil liability in their own legislation.
- Apart from the strict liability doctrine, when **a duty of care** is breached **tort law (duty of care/negligence) liability** applies.[27]
- In civil law litigation there could be involved many defendants according to the different roles that are played by the people involved in the manufacturing process. The possible actors intervened in the process of creation e.g. Careables itself, makers that created the device, designers, as well as any medical professionals that have been involved in the production of the medical device, might be held liable.

[24] For an wider description of the applicable laws, see D6.1.
[25] For a more detailed analysis of this notion, see D6.1, section 4.1.3.
[26] Art. 7(c) of the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (Product Liability Directive).
[27] For a wider overview of the concepts of 'duty of care' and 'negligence', see D6.1, section 4.1.2.

5.2.1.2. Recommendations: liability and warranty clauses

Recommendations on liability and warranty clauses for Careables makers and designers[28]
• Designers and makers should ensure that **warranties and warning clauses** – this in particular when the maker shares the project with other stakeholders (individuals, or different kind of communities) are included in their licenses. • Where appropriate, it is recommended to **write specific** (rather than generic) standard clauses. To the extent it is possible, users should be aware of risks, danger and damages that could be caused by objects related to an innovative solution like a Careable. • Usually, some license terms already contain **disclaimers** stating that the files are provided "as is", without fitness for a particular purpose. Only through the acceptance of risks, the licensee is allowed to make use of the files in the first place according to the conditions placed in the license. • **Warnings** could include:[29] - the product/prototype shall be used only for the purpose/aim that the designer/maker attributed to it; - a specific warning about the improper use of the experimental or innovative object; - a specific warning about the possible mistakes or defects in the design of the experimental or innovative object; - a specific warning that the user can use the specific experimental object "as is" on "his or her own risk" (this is also included in a typical license); • As a good practice[30], it might also be considered to subscribe for an **insurance** from risk of immaterial and material objects in the context of Careables.

6 Careables & medical devices

6.1 Introduction

The development of Careables may concern also certain items that, occurring some circumstances, might qualify as medical devices according to European law and/or national law on medical devices.[31] If a Careable falls under the definition of 'medical device', the relevant EU and national legal requirements may apply. However, the full application of MDL depends not only on as to whether a product is to be considered as a medical device, but also whether the person manufacturing the item has to be considered as a 'manufacturer' under the EU law. As

[28] The present table is drafted in the light of experience and findings descending from other analogous research projects in the DIY environment. See DiDIY, D6.1 –'Dominant legal challenges and solutions practised'.
[29] See ibid.
[30] Ibid.
[31] An overview of the medical devices legal framework has been provided in D6.1, section 4.3.2.

pointed out in D6.1 there is little legal certainty with respect to the role of designers and makers in the context of the Do it Yourself (DIY) environment.[32] As foreseen by the MDD, most part of MDL requirements apply to manufacturers placing a medical device into the market if operated in a professional context, i.e. the provision of goods "in a business related context".[33] The evaluation of this condition has to be performed on a case by case basis.[34] As European guidance documentation shows,[35] 'commercial activities' is understood as to providing goods in a business related context and also non-profit organisation might be considered as carrying out commercial activities. Nonetheless, it is explained that in principle "occasional suppliers by charities or hobbyists should not be considered as taking place in a business related context".[36]

The following paragraphs outline the legal definition of medical device in Europe and provide **practical guidance to evaluate: (a) whether a designer/maker should consider herself as a 'manufacturer'** as well as to **(b) whether an item falls under the EU definition of 'medical device'** according to EU MDL.

6.2 Careables & MDL

6.2.1.1. Definition of medical devices under MDL

The table below aims to provide a brief overview of the definition of 'medical device' according to European law. As outlined in D6.1, as of 2020 the Medical Device Regulation will become directly applicable in all EU Member States. Therefore, the table provides both definitions: the currently applicable one (under the MDD) and the one that will be applicable as of 2020 (under the MDR).

Definition of Medical Devices under the MDD and the MDR	
Medical device (MDD) [37]	"Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compen-

[32] The issue has been outlined and explained in D6.1 – see section 4.3.3.2.
[33] EC, Blue Guide on the implementation of EU products rules, 2016, p. 17.
[34] Ibid.
[35] Ibid.
[36] Ibid.
[37] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

	sation for an injury or handicap: investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."[38]
Medical device (MDR)[39]	"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."[40]

6.2.1.2. Legal analysis

A product will qualify as a medical device when intended by the manufacturer to be used **specifically** for a **medical purpose.** The MDR notion differs slightly from the MDD one. It now includes a reference to the "prediction and prognosis of a disease". Also, the new definition includes the 'implantable medical devices', which formerly was treated in a different piece of legislation.[41] Important to underline is that an object qualifies as a medical device when it is intended by the **manufacturer to be used for medical purposes**. The medical purpose is **assigned to a product by the manufacturer**[42] and relates in general to **finished products,** regardless of whether they are intended to be used alone or in combination with other devices.[43]

[38] Art. 1(2) MDD.
[39] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
[40] Art. 2(1) MDR.
[41] Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC). See also D6.1, p. 67.
[42] For further considerations about the notion and figure of manufacturer, see D6.1, section 4.3.3.1.
[43] MEDDEV 2.1/1, April 1994, Guidelines relating the application of: Council Directive 90/385/EEC on active implantable medical devices, the Council Directive 93/42/EEC on medical devices, p. 3.

Another condition that qualifies a medical device is a negative one: the item/device **must not "achieve its principal intended action by pharmacological, immunological or metabolic means**". This condition has been introduced by the EU legislator with the aim to differentiate 'medical devices' from 'medicinal products'[44] in order not to create a legal gap between the two categories.[45] Whether an item/product qualifies as a medicinal product (because it is use with a view to preventing, treating or acting on diseases by exerting a pharmacological, immunological or metabolic conditions), it is likely not to be qualified as a medical device. In many case, the distinction between the two categories is not easy to draw.[46]

6.3 MDL Guidelines

The table below is divided in three areas: (1) personal scope; (2) material scope; (3) core question. The first area ('**personal scope**') aims at verifying whether a designer or a maker should consider himself or herself as a 'manufacturer' in the meaning of MDL. As already outlined in D6.1, according to MDL a manufacturer is "the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party".[47] The notion of 'manufacturer' and 'placing on the market' under MDL have been already analysed in D6.1 (we refer to section 4.3.3.1 'Manufacturing' for a detailed analysis thereof) as well as in the introduction of section 6. Key element proposed by the table to be analysed is whether the subject after creating the item, puts it "on the market", i.e. operates in a "business related context" (see introduction to the present section). The second area ('**material scope'**) aims – by taking into account the MDL definition of medical device delineated above – at verifying the nature of the device, whether it will be used by human beings, and its principal intended action (as analysed in the section above). The third area ('**core question**') is intended to help the manufacturer establish whether the device will be used primarily and specifically for 'medical purposes' within the meaning of the

[44] See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. For the definition of 'medicinal product' see Art. 1(2) thereof: "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

[45] For an analysis of this aspect, see D. Eskenazy, Le dispositif médical à la recherche d'un nouveau cadre juridique, Droit. Université du Droit et de la Santé - Lille II, 2016. Français. NNT : 2016LIL20014.

[46] In many cases, the distinction between the two categories is not easy to draw. To such regard, along with the relevant case law, it is useful to consult the EC guidance documentation in the matter, and particularly the recently issued (May 2019) EC Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 (05-2019).

[47] Art 1(2)(f) MDD.

EU MDL – which may range from the diagnosis, prevention, monitoring, treatment or alleviation of disease to the diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, to the investigation, replacement or modification of the anatomy or of a physiological process, to the control of conception.

Questions to evaluate the MDL scope and applicability	
Personal Scope	
(0) Manufacturer – Business related context	Are you providing goods in a business related context? To evaluate this question, the following elements may be taken into account: • How often goods are supplied? frequently? • What are the characteristics of the product? • What are your intentions as supplier? * In principle, occasional suppliers by **charities or hobbyists should not be considered** as to operate in a business related context.
**If you or your entity operates in a business related context → answer to the questions (1), (2) and (3)*	
Material Scope	
(1) Nature of the device	Is the object in one of the following **categories**? • Is it an instrument? • Is it an apparatus or an appliance? • Is it a software? • Is it an implant, a reagent, or a material?
(2) Usage by human beings	Is the item intended to be **used by human beings**?
(3) Principal intended action	Is its principal intended action achieved not by **pharmacological, immunological or metabolic means**?[48]
**if your answer is YES to both questions (1), (2) and (3) → answer to the question (4)*	
Core question	
(4) Purpose of the device	Is the item intended to be **principally** used for a **specific medical purposes?**

[48] For further guidance, see also EC, Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices. Version 1.22 (05-2019).

[disease]	- Is it intended to make a diagnosis or a prognosis of a disease? - Is it intended to prevent or predict a disease? - Is it intended for monitoring, treat or alleviate a disease?
[disability]	- Is it intended to make a diagnosis or to monitor a disability? - Is it intended to treat, alleviate or compensate a disability?
[injury]	- Is it intended to make a diagnosis or to monitor a disability? - Is it intended to treat, alleviate of, or compensate an injury?
[anatomy]	- Is it intended to investigate the anatomy? - Is it intended to replace or modify the anatomy?
[physiological or pathological process or state]	- Is it intended to investigate , replace or modify a physiological or pathological process or state?
**if your answer is YES to any of the questions under (4) → consider applying the MDL requirements.*	

6.3.1. Practical examples

In addition to the guidelines provided above, it is provided below a table of examples to facilitate the understanding for professional makers or designers or manufacturing entities of what could be classified as a medical device. These examples are based on the EC MEDDEV Guidance document of medical devices. [49] [50] To enhance its practical impact, a parallel with some possible examples of Careables is listed therein. As stressed above, this table reveals to be useful for whom should consider themselves as 'manufacturers' of medical devices, as defined by EU MDL.

Examples of items that, occurring certain circumstances, may qualify as medical device[51]		
Category	**Exemple**	**Careable**
Devices that either do not touch the patient or contact intact skin only	Devices used to immobilise body parts and/or to apply force or compression on them (e.g. cervical collars, gravity traction devices, compression hosi-	*'TooWheels'*

[49] MEDDEV 2. 4/1 Rev. 9 June 2010, MEDICAL DEVICES: Guidance document - Classification of medical devices.
[50] Also, to have an enhanced overview of medical devices examples, further information may be retrieved on guidance documents issued at national level by National Competent Authorities. For example, the Italian Ministry of Public Health set a medical devices national legal inventory. The consultation thereof might provide further clarifications and exemplifications for understanding the scope of medical device definition.
[51] See Ibid. Categories and Exemplifications are reported from the same document. Note that the table has been drafted for explanatory purposes only. For a further in-depth analysis and explanation of the specific medical device cases and classification criteria, it is suggested to refer directly to Annex IX and the MEDDEV Guidance document on Classification of medical devices.

	ery); Devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chairs).	
Devices invasive with respect to body orifices	Suction catheters or tubes for stomach drainage.	*'Stomanoir'*
Active therapeutic devices intended to administer or exchange energy	Warming blankets; blood warmers.	*'Stress-Reducing Weighted Blanket'*
Examples of items that occurring certain circumstances may not qualify as medical device[52]		
Products intended for a toiletry or cosmetic purposes	Tooth brushes, dental floss, instruments for tattooing, baby diapers or hygiene tampons.	*'Toothbrush Adapter'*
Equipment alleviation or for compensation for a handicap, not having a direct link between the corrective function and the person concerned.	Special water taps	*'Plastic bottle opener for hand support'*

7 Conclusions

With reference to the legal requirements studied above, it may be concluded as follows. PDP law is a determinant aspect to be considered before, during and after the execution of data processing activities related to the Made4You project. Makers and designers should also keep in mind PDP while co-designing and creating a Careable. Concerning IPRs, it is suggested for makers and designer to consider the adoption of Creative Commons licenses, as most appropriate tools to protect their rights while sharing knowledge on Careables. When it comes to TLT, establishing roles in the DIY environment becomes difficult due to legal uncertainty in the field. Key considerations stress the fragmentation of the legal requirements in the DIY environment, where makers and designers liability should be evaluated on a case by case basis. To this regard, makers and designers should also verify liability and warranty clauses for Careables to limit, where possible, their liability. Finally, the MDL Guidelines highlight that the MDL

[52] Examples and guidance is retrieved from MEDDEV 2.1/1, April 1994, Guidelines relating the application of: Council Directive 90/385/EEC on active implantable medical devices, the Council Directive 93/42/EEC on medical devices.

requirements become applicable if: (i) a subject or entity is considered as a ‘manufacturer’ according to the EU MDL and this occurs when it acts in a business related context or runs a commercial activity with Careables – in principle, occasional suppliers by charities or hobbyists should not be considered as such; (ii) an item is ascribable to the ‘medical device’ definition provided by MDD and MDR.

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