eHealth HUB Smart Guides

FIND YOUR WAY THROUGH THE EHEALTH MARKET

Guidelines to frequent legal and regulatory challenges of European eHealth SMEs

eHealth HUB
European eHealth business support.

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Index

1 About us

We are here to support European eHealth businesses

eHealth HUB - European eHealth business support is the new EU-funded initiative, cross-border and focused on the digital health vertical. eHealth HUB's goal is to provide high-quality business-oriented services tailored to the needs of European eHealth startups, SMEs and stakeholders. We use a demand-driven approach to promote new business and collaboration opportunities for SMEs and key ecosystem stakeholders including healthcare provider organizations, investors, insurers, pharma and med-tech.

info@ehealth-hub.eu
www.ehealth-hub.eu

From Business Modelling to Regulatory advice: exploit our services

eHealth HUB offers FREE services to support European eHealth SMEs, healthcare providers and ecosystem stakeholders on the following key areas:

Business modelling

Business model clinic
One-on-one Support

The Business Model Clinic supports the best promising entrepreneurs and startups offering personalized coaching on business proposition, customers and go-to-market strategies.

Lean Startup Academy
Learn to be Lean

The Lean Startup Academy provides eHealth SMEs with the opportunity to mature their business by systematically testing their ideas against the market.

Access to private finance

Investment readiness training & pitch
Make eHealth SMEs ready to make their business

eHealth Hub Investment Readiness prepares European early-stage startups and SMEs to approach and collaborate with investors.

eHealth Hub Platform
The place to be for eHealth SMEs and Investors

The eHealth Hub Platform features SMEs, investors, healthcare organizations, legal and regulatory service providers. By registering, health stakeholders can get easily in touch with each other.

Commercialization

Solution Match
Start form your need, ask European SMEs for a Solution

Solution Match supports healthcare providers, insurers, pharma or medtech companies looking for a concrete digital health solution to be implemented in their organization.

eHealth Roadshow
Pitch your solution, Jump into European market

eHealth Roadshow offers an opportunity for selected eHealth SMEs to expose their digital health solutions in front of a Committee of key stakeholders in the eHealth European market.

Legal issues & Regulatory and reimbursement guidance

Legal Support
A compass to navigate legal services through Europe

eHealth Hub Legal Network offers good quality, affordable legal advice for eHealth SMEs as well as free workshops detailing current legal issues of eHealth SMEs interest.

Regulatory Guidance
Regulatory and Reimbursement Guidance for eHealth SMEs

eHealth Hub Regulatory Network helps European eHealth SMEs to be compliant with regulatory requirements and develop reimbursement strategies across the European Union.

Let's find the best way to work together

***Jorge González**,*
eHealth Hub coordinator
and eHealth Hub team

"At eHealth HUB, we believe that health organizations, public administrations, private companies, professionals, and patients all form a huge ecosystem: we cannot 'grow' without each other. That is why eHealth HUB works as a network of relevant stakeholders within the eHealth ecosystem to work together in order to boost eHealth in Europe. Therefore, if your business is in digital health, contact eHealth Hub. We'll find the best way to work together".

2 Why this report?

"Compliance is a top priority in eHealth. European manufacturers of digital health technologies must comply with all laws and regulations applicable to their operations and business activities. In addition to the local laws many European Union rules apply directly. Laws and regulations can however often be difficult to understand for entrepreneurs, which makes outsourcing one of the best options. But, where do you go to? We identified the need for affordable specialized advice and created two networks of experts in Europe, available to help solve your legal & regulatory challenges. The first network is dealing with legal advice ("legal network") on topics such as data protection and intellectual property rights. The second network is dealing with CE-certification for medical devices ("regulatory network").

Over the last 24 months, we have organised many workshops around Europe and offered guidance to 98 SMEs. We have learned a lot from the questions SMEs raised. The two main challenges to digital health SMEs were the new General Data Protection Regulation (GDPR) which came into force 25 May 2018 and the new Medical Device Regulation (MDR, 2017/745/EU) which came into force one year earlier on 25 May 2017. Additionally, Intellectual Property Rights (IPR) and further Medical Device related topics are real challenges to SMEs. The main pitfall is their practical implementation. The most frequently asked question was: How do you do that? We all struggle with the practical implementation of regulations, but with this guide and our legal and regulatory network we can help you.

We have summarised the most interesting case studies on legal and regulatory topics for you, to give an insight into the questions SMEs have and how these can be solved. We are introducing five cases on legal topics to you, these include: **3 cases on GDPR and 2 cases on Intellectual Property Rights**.

Furthermore we **are highlighting 4 important topics along the road to a CE-marked medical device**:

- 2 cases on the question is my software a medical device and if so, what class does it fall into according to the "old" Medical Device Directive (MDD; still in force until 25 May 2020) and the new MDR.
- 1 case dealing with the description of the Intended Use of the medical device
- 1 case dealing with the question how to compile the Technical Documentation.
- 1 case summarizing the requirements to establish a quality management system according to ISO 13485.

Are you also struggling with any of these topics?
We are here to help!

If you need help with **legal issues such as the GDPR or Intellectual Property** , just reach out by registering here. If you need help with **medical device related questions** register here.

We will guide you to an expert in our eHealthHub network specialised in the area of law you are enquiring about."

Give it a try!

3 Legal Case Studies on GDPR and Intellectual Property

1 Case Study — GDPR

2 Case Study — GDPR

3 Case Study — GDPR

4 Case Study — Intellectual property rights

5 Case Study — Intellectual property rights

1 Case Study

GDPR

The Client

A start-up based in the Netherlands, with an aim to empower patients. This start-up connects medical students to patients and help them before, during and after a doctor's visit.

Regulatory challenges

The client was selected for the Clinic startup support program in 2018. The client was aware that he needed advice on GDPR. In particular, the client wanted to have information on the practical implications of the data protection rules. The client received legal advice on data protection (GDPR) and local Dutch medical liability regulation.

Advice

The client received written advice (memo) on the legal implications of their way of working: which regulations apply regarding their liability. Secondly, they received advice on data protection. This included what data can be used on their platform and how to process this. The client has received a written memo, explaining applicable law and the important results / recommendations / practical tips. This memo gives an overview of the rules that apply and the risks the start-up is encountering. The start-up can use this memo to start their internal compliance processes. The key identified issues regarding GDPR compliance are:

- GDPR is applicable to their services and platform;
- Client should request explicit consent from its customers for the processing of personal data;
- Client should provide its customers with an overview of information about their services;
- Client should open up the platform to its customers; and

Client should organize the platform in such a way that the medical students will not be in a role of advising on or interpreting medical information.

SME Feedback

"Legal advisors Gianna & Gijs made the clinic legal program both useful and fun. The memo they provided is a solid base to further evaluate the legal issues of our startup. It is both professional yet easy to read and understand, which is important for me since my knowledge of law is poor. I know I gave them a hard case but, with the help of two lawyers from law firm Boekx, they did an excellent job." - Managing partner

2 Case Study

GDPR

SME Feeback

"When we were trying to raise fund, we almost released information about our technologies to all the people we were meeting in order to convince them to invest in us. Attending qLegal webinar and then teleconference advice session certainly helped us realised we should not. If you want to patent the software, you need to make sure it hasn't been publically released. It was important for the sustainability of the business to get a patent first."

"At the very beginning of the venture, I almost went into the wrong concept of vesting with an investor. Getting advice on shareholding agreement with early investors from qLegal helped me make decision for my business, to not accept giving away equity against a non-specific amount of funding. "

"Not being able to access legal advice can mean losing real opportunities. Before my appointment with qLegal I didn't know what information we should keep quiet about, and how to navigate the business environment."

The Client

A start-up based in the Netherlands, they developed a solution for the Blind and Partially Sighted, to pursue a joyful life with more independence. They developed an artificial intelligence app with the aim of blind and partly sighted people to help discover their environment with 'deep learning-based computer vision' to create objects, people and emotions recognition. It works like this: the camera must be directed towards something or someone, and the app will speak out loud to the user what or who is pointing to.

Regulatory challenges

The client was aware that the product gathers personal information, such faces, names, skin colour etc. and needs to know which requirements have to be met in order to comply to the data protection regulation.

Advice

The client received a written advice memo, explaining the data protection rules that apply and the necessity of a privacy policy in the app. The advice was put into practice with developing a Privacy Policy for the app.

SME Feedback

"We really appreciate the work of the Clinic advisors and law firm Axon. We would not have been able to understand the risks and implications without this advice. This was a very good lesson on risk assessment."

3 Case Study

GDPR

The Client

The client's business is a messaging app which aims to promote conflict-free conversation. Artificial intelligence within the chat application acts as a mediator during the discussion. The artificial intelligence looks for things like mood, the speed of the conversation and whether either party is misunderstanding the other. It then makes a suggestion on how to neutralise the conversation.

Regulatory challenges

The client's purpose for receiving advice was to prepare for the General Data Protection Regulation (GDPR).
They wanted to monitor, and analyse conversations occurring in the chat and use this information to improve the app's performance. The client wanted to know the best way to inform their users of this behaviour in their privacy policy.

Advice

The client received advice on the main changes that GDPR made and how the client should implement them.
This included the seven over-arching principles that must be met in order to comply with the data protection laws. They were also informed that they would be a data controller and this meant they must satisfy certain conditions contained the GDPR.
The client was advised that some of the information discussed in the app would be considered 'sensitive personal data' and that they were therefore subject to more stringent conditions.
The main changes the client were advised to implement were:

1. Appointing a data protection officer.
2. Reporting data breaches.
3. Gaining positive consent from the app users.

The clients were advised on their legal liability regarding encryption. They were advised to undertake a risk assessment, which balanced the risks and benefits of applying/not applying encryption. They were also advised that an alternative was to limit access to the data to those who have a legitimate interest to access it.
The client's business uses artificial intelligence. The client was advised they must identify precisely which parts of the program include automated individual decision making and include this information in their privacy policy. They also got general advice on how to draft a privacy policy, and what to include.

SME Feedback

"We really appreciate the work of the Clinic advisors and law firm Axon. We would not have been able to understand the risks and implications without this advice. This was a very good lesson on risk assessment."

4 Case Study

Intellectual property rights

The Client

A start-up based in Ireland, they developed a wearable that gives real-time biofeedback on the user's breathing patterns.

Regulatory challenges

The client was aware of the fact that he needed to file a trademark in the US, but wanted to check with an expert if they were on the right path, they wanted to know what their chances were of being granted the US trademark or if they should expect oppositions and limitations.

Advice

The client received advice on the process of trademark filing in the US, from experts at Brooklyn Law School Incubator BLIP and professor Linda Braun. The advice contained the chance of receiving the actual US trademark and if they should expect oppositions & limitations. The experts explained the process of trademark filing and advised on how the US trademark should be filed to expect minimal chance of opposition & limitations. The client filed the trademark himself, because he was well informed and in a rush. If necessary the experts could have filed the trademark together with the client, because it is important to make the right choices. It is not necessary to hire a trademark lawyer to file a trademark, either in the US or Europe, but it hears to specific knowledge to do it in the right way. The aim is to limit the chance of opposition and this can only be done by an expert research before filing. That is why we always advice to work with an expert before filing a trademark.

SME Feedback

"Thank you for reaching out to your network in the US! This was exactly what I needed, my legal challenge is solved within a few days, amazing!"

5 Case Study

Intellectual property rights

The Client

Immersive Rehab develops interactive games in Virtual Reality. With these programmes, Immersive Rehab intends to improve the effectiveness of physical rehabilitation, by providing a motivating solution to people who have neurological limitations.

Legal challenges

The client wanted to understand how to protect VR games with different IPRs, how to draft Terms and Conditions for their website, and the data protection implications of collecting and storing data on the cloud.

Advice

The client received an overview of the available IPR protection options with respect to trade marks, patent, copyright and design protection in the UK.

The client was given guidance on intellectual property rights. Some of which arise automatically, such as copyright and design rights, whilst others require registration in order to be enforceable, such as trademarks, registered designs and patents.

The client was advised that English law offers copyright protection for software but that it is hard to obtain in practice. Indeed, this protection encompasses primarily the copyright in the embedded code. This code relates to the software as a whole as well as to all features of it, including function-specific parts, the graphical user interface, the artwork, the music score, the spoken words. Therefore, copyright protection may cover the code in its entirety and/or any or all of the above individual features. Often features of the software, particularly video games, can be recreated without accessing the source code - or even using the same source code. In such cases, copyright protection appears to be limited.

The client was also advised on the trademark protection of her sign and logo, and what can and cannot be registered as such. The client was made aware of additional requirement regarding prior art (to avoid infringing on someone else's rights) as well as the cost involved to register a trademark with the UK Intellectual Property Office (UKIPO).

Regarding the patenting of the client's software, the client was advised the patent application process is complicated and there are many formal requirements to be met.

Advice

It was also recommended that the client files a new patent application with a search request so that the UKIPO or EPO will produce a search report before she needs to decide whether to seek foreign patent protection. The search report would assists the client in making this decision. She is likely to benefit from the services of a patent attorney that would help her understand the relevance of the documents referred to in the search report.

Further information detailing the patent application process can be found on qLegal's resources webpage at http://www.qlegal.qmul.ac.uk/docs/123220.pdf. The UKIPO's webpage provides more details with regards to basic costs related to a patent application in the UK, at https://www.gov.uk/government/publications/patent-forms-and-fees/patent-forms-and-fees.

The client was advised she should create a formal agreement, specifically an NDA and collaboration agreement between the parties she plans to collaborate with in developing her product, as well as an NDA and services agreement with any third parties to which she is offering the product. It was also recommended to implement T&Cs.

The client also received advice on data protection. To determine whether the client was in fact a data controller and should register with the ICO, the client has to assess whether her business is responsible for the data that her Providers generate through usage of the Product and the purposes for which it is used.

In this case, the client was also advised to make it clear, in the Terms and Conditions and Privacy Policy to be signed by their Providers, that the client is not the data controller, or data processor of the data since they do not record or process the data. The letter also detailed the distinction between "personal" and "sensitive data", in order to apprehend the different legal implications this has for the client's business and Providers. If the client wanted her own customers to be able to access their own data directly through the client's app, the client would need to assess whether she is a data controller. If the client is able to process personal data (by collecting it, storing it and sharing it), and to do so electronically (by which the advice letter means using "computers or any system that can process the information automatically, including CCTV systems, digital cameras, smartphones, credit card machines, call logging and recording systems, clocking machines and audio-visual capture and storage systems".). The client was also advised that for the moment it is unclear how Brexit will affect the application of the GDPR given that it stems from the EU. The client was recommended to seek further legal advice in this respect closer to the initiation of the GDPR.

SME Feedback

"I actually found out about qLegal when I met one of the members in person in a professional event. I was told that the services were performed by students and supervised by practitioners, which led me to trust that they would always have up-to-date knowledge and information regarding my legal issues. That is exactly what I needed, considering that my business area is still very new and does not have many precedents."

"I was very happy with everything, from the moment I submitted my case, to the final advice letter being sent to me. My schedule is busy and sometimes appointments had to be changed, which the qLegal members were always very comprehensive about. The advice letter provided me with advanced information regarding my business current demands and went even into more detail than I was expecting. Everything was very well written and I plan on going back to consulting the letter from time to time, when facing any issues again. I really appreciate all the attention from qLegal and would definitely recommend your services to any startups, as a good source of quick, easy and accessible professional legal advice."

4 Regulatory Case Studies

1 Case Study — **Classification according to MDD vs. MDR**

2 Case Study — **Classification according to MDD vs. MDR**

3 Case Study — **Intended Use description**

4 Case Study — **Required information in the Technical Documentation**

5 Case Study — **Implementation of an ISO 13485:2016 Quality Management System**

1 Case Study

Classification according to MDD vs. MDR

The Client

The digital health SME developed a software solution for the intelligent provision of surgical patient information via standard Augmented Reality glasses. By using the solution, the surgeon will be able to perform the procedure more efficiently by doing the bone cuts instantly exact and positioning hip and knee implants more precisely.

Regulatory challenges

The client was aware that the product will most probably be a medical device. He needed to know how to classify the medical device and which regulations have to be considered. In particular, the client wanted to have information on changes from the old Medical Device Directive (MDD) to the new Medical Device Regulation (MDR) regarding the classification and when they have to comply with the new MDR.

Advice

The client received advice on the medical device regulatory framework and an assessment of the classification of the medical device according to the MDD and MDR.

1. Medical Device Directive (93/42/EWG)

The intended use of the software is to support in the process of a surgery by providing patient data. As it is specifically intended to accompany and indirectly affect a treatment, the intended purpose for a medical device would be fulfilled.

Considering only the functionality itself, the product cannot be classified as a medical device yet, i.e. with a different intended use the classification as medical device could be circumvented. However, it has to be noticed that a product which is not classified as a medical device, can neither be marketed nor applied for medical purposes.

Medical device software is always considered an active medical device because the operation of the software depends on the power supply of the hardware. As the software accompanies the treatment, it would be an active diagnostic medical device.

Rule 10 classifies active diagnostic medical devices, but none of the sub-rules can be applied to the software. Rule 12 would therefore apply and the software would be class I in the case of a medical device classification.

2. Medical Device Regulation

The Medical Device Regulation was issued in May 2017. From May 2020, all medical devices have to be placed on the market in compliance with the MDR. Medical devices that are placed on the market before the cut-off date may still remain on the market in accordance with the provisions of the MDD and depending on the classification, they may remain on the market for 3 to 5 years before the manufacturer has to meet the new requirements mandatory.

Advice

The definition for medical devices is the same as in the MDD. However, classification rules change, in particular for software. For the same intended use, the software would probably be in class 2b. An incorrect decision, based on the displayed information, could lead to severe deterioration or the need for further surgical intervention. Even if the software does not process the information, the way it is displayed could affect decisions made during the operation (e.g. if images are too small or blurry, details
may be overlooked). This rule does not have to be applied yet, but should be considered for long-term planning.

In this case, the **change of classification of the medical device software from MDD** (class 1) **to MDR** (class 2b) would have a **significant operational and financial impact on the SME** regarding the CE certification of the medical device.
For class 1 certification, a self-declaration of conformity of the SME is sufficient, including a confirmation that the product is a class I medical device, meeting essential requirements, carrying out a clinical evaluation, prepare technical documentation etc..
For higher medical device classes (2a, 2b, 3) the declaration must be backed up in all cases with conformity assessment by a notified body (public or private organization that has been accredited to validate the compliance of the medical device to the European Directive). This includes the establishment of a Quality Management System according to ISO 13485:2016. It represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. Furthermore, the SME has to appoint an employee as an authorized representative which implies that one employee should exclusively work on the CE certification process and all internal procedures for complying with the Medical Device Regulation and conducting annual audits with the notified body to ensure compliance.
Hence, for complying with the requirements for class 2a, 2b or 3 medical devices CE certification, SMEs have to invest a lot of time and money which is a huge challenge, in particular for startups which often have only a few financial and personnel resources.

2 Case Study

Classification according to MDD vs. MDR

The Client

The client developed a software solution for patients suffering from tinnitus which embeds the tinnitus frequencies harmoniously in music and thus allows immediate relief of tinnitus pain - melodious, self-determined, customizable, and combinable with hearing aids.
Affected persons can enjoy musical breaks with tinnitus at any time with the app (mobile, PC) and headphones or hearing aid. The selectable music is automatically evaluated and edited to play around the Tinnitus tone. This allows concentration on the positive listening experience while tinnitus is perceptibly in the background.

Regulatory challenges

The client was aware that the software has to be certified as a medical app. He was not sure how to classify the app as standalone software, neither according to the Medical Device Directive (MDD) nor to the Medical Device Regulation (MDR). In particular, the client needed to know if there are any changes from MDD to MDR regarding the classification and the requirements for compliance.

Advice

The client received advice on the classification of the software as a medical device according to the MDD and MDR.

1. Medical Device Directive (93/42/EWG)

The intended use of the software is to relieve subjective tonal tinnitus. Hence, according to the MDD, the app is a medical device as the definition of the medical device includes the alleviation of diseases.
According to the regulatory provisions of MDD, software is generally considered an active medical device because it relies on an electrical device (PC, tablet) for operation. Despite the therapeutic use, the classification as an active therapeutic medical device can be excluded as this product has no effect on biological functions or structures.
Classification rules 9-12 refer to active products. Rules 9-11 are not applicable here as there is no active therapeutic nor active product nor interaction with pharmaceuticals. Hence, Rule 12 applies as the highest usable rule. This rule states that all other active devices are in class 1. Thus, the software is a class 1 medical device according to the MDD.

2. Medical Device Regulation

In order to determine the class of the software as a medical device according to the MDR, rule 11 is crucial as it comprises software specific classification rules. It says:
"Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

Advice	◇ death or an irreversible deterioration of a person's state of health, in which case it isin class III; or ◇ a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb. Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software are classified as class I." According to the intended use of the software, it is not designated to provide necessary information for diagnostic or therapeutic purposes. Furthermore, the software does neither monitor physiological processes nor physiological parameters. Hence, if the intended use is limited to relieving tinnitus symptoms, a classification as class 1 medical device should also be possible according to the new MDR. In this case, the classification of the medical device software does not change from MDD to MDR which means that for the CE certification a self-declaration of conformity is still sufficient, even under the new MDR.
SME Feedback	"It is great to know these facts and this helps us for the future planning." "Thank you very much! Your advice is really helpful. I will come back to you if I need more support."

3 Case Study

Intended Use description

The Client

The client developed an intelligent health assistant. Based on sensor data fusion and individual interpretation, the smartwatch app supports daily life, therapy and risk detection.
It allows automated health monitoring, easy integration of your individual network and direct notification if needs be. Furthermore, it identifies relevant incidents in heterogeneous sensor data – suit-tailored to each indication. This way, the software eases therapy assistance, adherence and success.

Regulatory challenges

The client was not sure if the smartwatch app as a software itself is a standalone medical device if it is integrated into a system and how to describe the intended use of the product. Furthermore, the client needed to know how to compile a user manual for the software as a medical device.

Advice

The client received advice on how to describe the intended use of the product so that the smartwatch app is a standalone medical device and guidelines for the description of the user manual for the software.

1. Intended Use and classification as standalone medical device. The application of classification rules is valid for the old Medical Device Directive and the new Medical Device Regulation:

- ◇ application of classification rules depends on the intended use of the product
- ◇ If the product is intended to be used in conjunction with another product being applied, the classification rules apply to each product applied separately.
- ◇ Software that controls a product or affects its application becomes the same class as the product
- ◇ if the software is independent of other products, it will be classified on its own

Hence, in the description of the intended use of the product, it has to be explained if and how the product interacts with other products. Thus, providing information about an existing interface would not be critical, since there is no control or influence on the other product.
However, if the connected device or program would perform certain actions automatically, based on this information, such as an alarm on an ECG monitor, there would be an influence on the application (user acts in response to the alarm, or omits actions because of the absence of the alarm).

Advice

For the description of the intended use for medical devices, the following issues should be considered:

- intended medical benefit, like the product of the diagnosis, therapy, monitoring of diseases and injuries
- typical use case
- physical principle - regarding apps, the algorithm
- functions and features
- restriction and limitation of application
- Intended user population
  - oUser group (patient, doctor, health professionals)
  - oSpecific diseases
  - oGender, age groups and other relevant descriptions of the population
  - Necessary education or experience, knowledge level etc.
- context of use (clinical, outpatient, at home)

2. Guidelines for description of user manual

The following sources of industry associations and authorities/agencies for policies and regulations regarding the content of user manuals and product labelling of medical devices should be considered (some of them in German language, as the client is from Germany):

- Zentralstelle der Länder für Gesundheitsschutz bei Arzneimittel und Medizinprodukten (ZLG)
- Bundesverband Medizintechnologie (BVMed)
- UK Medicines and Healthcare products Regulatory Agency (MHRA)
- US Food and Drug Administration (FDA)
- Global Harmonization Task Force / International Medical Device Regulators Form (GHTF / IMDRF)
  - GHTF/SG1/N43:2005 - Labeling for Medical Devices
  - GHTF-SG1-N009R6 - Labeling for Medical Devices
  - SG1/N011R17 - Summary Technical Documentation for Demonstrating Conformity to the essential Principles of Safety and Performance of Medical Devices (STED)
  - GHTF/SG1/N70:2011 - Label and Instructions for Use for Medical Devices
- Following standards
  - EN 980 - Symbols for use in the labelling of medical devices
  - EN 15223-1 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
  - EN 1041 - Information supplied by the manufacturer of medical devices

4 Case Study

Required information in the Technical Documentation

The Client

A start-up based in Germany, developed an innovative and patented medical ophthalmology device that will provide physicians with optimal support in the future when implanting artificial lenses in the treatment of cataracts.

Regulatory challenges

The client is aware that the product is a medical device and needs to know which requirements have to be met in order to achieve CE certification of the medical device.
In particular, the client needs to know which information is required for compiling the technical documentation.

Advice

The client received advice on which information is required for the technical documentation. Following a telco for clarification of initial questions, the client received a checklist for the technical documentation.
The technical documentation includes all necessary and useful information about a product and its manufacture and use, which are recorded in a structured form. It serves as proof of the fulfillment and conformity of the medical device with the applicable guidelines and may be investigated by notified bodies or authorities.
The preparation of a technical documentation or comparable collection of documents is required for all products that are put into the European market in accordance with the requirements of the Medical Device Directive 93/42 / EEC (Annex VII). The documentation shall be compiled prior to the launch of the product and shall be kept in an appropriate form which, upon request from authorities, allows for short-term delivery.
There is a 5-year retention period from the date of manufacturing the last product.
The guideline describes the minimum requirements for the contents of the technical documentation but makes no specifications regarding the concrete content and structure of the documentation. The adequacy of the documentation in terms of product and requirements to be met must be determined and ensured by the manufacturer.
The technical documentation includes in particular:

- a general description of the product, incl. different modifications and intended use
- design and manufacturing drawings and plans of components, assemblies, circuits

- ◇ descriptions and explanations necessary to understand drawings, plans and functionality of the product
- ◇ results of the risk analysis and a list of fully or partially applied standards in accordance with Article 5 and a description of the solutions to the essential requirements of this Directive
- ◇ if the products are placed on the market in a sterile condition, a description of the procedures used and the validation report
- ◇ results of the design calculations and tests, etc. If a product must be connected to one or more other products to fulfill its intended purpose, proof that the former product, when connected to another product, conforms to the characteristics specified by the manufacturer fulfilling the basic requirements
- ◇ the preclinical evaluation
- ◇ the clinical evaluation according to Annex X
- ◇ labelling and instructions for use

Advice

There are various guidelines that can be used to set up the documentation. These are not required by law, but the use of an established structure can be helpful if the documentation needs to be evaluated for certification by a Notified Body. Some guidelines are as follows:
Guideline der Global Harmonization Task Force (GHTF)
http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n011r17-conformity-to-safety-principles-medical-devices-021025.pdf
Canada / STED
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-preparation-summary-technical-documentation-class-premarket-medical-device-licence-applications-vitro.html#a21
NB-MED / STED
http://www.team-nb.org//wp-content/uploads/2015/05/nbmeddocuments/Recommendation-NB-MED-R2_5_1-5_rev4_Technical_Documentation.pdf
mdc-ce (German notified body)
https://www.mdc-ce.de/fileadmin/user_upload/Downloads/mdc-Dokumente/Formulare_Recommend/140017_00_d_Inhalte_Technische_Dokumentation_93-42_98-79.pdf

SME Feedback

"Our telco and the documents are an important help for us, I really appreciate it. In addition, I would like to thank you for the phone call and the great advice again. Thank you for your offer to contact you again for further questions. We will stay in touch."

5 Case Study

Required information in the Technical Documentation

The Client

The client developed a digital health ecosystem, comprising different solutions for general medical, outpatient, inpatient, medical specialist and nursing services as part of an interdisciplinary cooperation with offers for prevention, rehabilitation, drug administration etc. This is implemented by several software modules that operate among themselves.

Regulatory challenges

The client has already registered some products as class I medical devices by self-declaration of conformity. The client would like to achieve CE certification for parts of the ecosystem as class II medical device and needs to know how to establish a quality management system according to ISO 13485.

Advice

The client received advice on how to introduce a quality management system according to ISO 13485 including an operation plan/time line, requirements specification and estimation of certification costs.

ISO 13485 an international standard that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices. It includes risk management according to ISO 14971.

1. Requirements Specification for quality management system according to ISO 13485

The requirements specification includes system requirements (company's requirements, QM documentation), management responsibilities (obligations, external requirements, quality policy, QM strategy, management requirements, management evaluations), resource requirements (requisition, staff, infrastructure, working environment), product realisation (planning, customer and development requirements, procurement and suppliers steering, product requirements, guidance of monitoring and measurement equipment), measurement and capture (planning, data collection, non-conform products, data analysis, continuous improvement).

2. Risk Management according to ISO 14971

ISO 14971 describes the process which is necessary for the risk management of medical devices. All documents and records kept during the implementation of the risk management process are collected in a risk management file. This can be part of the technical documentation or as a separate collection of documents.

The process includes a documented risk management plan, risk identification and analysis, risk evaluation, risk control, risk assessment, risk-benefit analysis, risk management report and information on the production and downstream processes.

3. Certification Costs

All following values listed are estimates based on experience for a company with one site and no critical sub-suppliers. Actual fees and charges are different for each certification authority and must be determined by requesting a quote.

Advice

For certification or re-certification, incl. evaluation of quality management documentation, audit plan and audit report, audit on-site (1,5 days) and issue of certificate, small companies (up to 15 employees) have to pay between 4.600 and 6.500 €, depending on the number of employees. Furthermore, for monitoring audits (in between certification audits), incl. audit plan, audit report and audit on-site, companies with up to 15 employees have to pay between 2.400 and 3.400 €, depending on the number of employees.

Additional costs might occur, e.g. travel costs, additional efforts for audits (e.g. several locations of the company, suppliers/subcontractors to be audited or additional audits) or issuing other certificates or subsequent changes of certificates.

Concluding remarks

To summarize we can state that solving legal as well as regulatory aspects is highly important to be successful in the eHealth environment. It is a highly regulated area, so compliance should be a top priority to avoid expensive complications at a later stage.
The legal environment has changed a lot over the last few years, data protection has become a global topic of discussion and focus. Processing people's data and especially medical data lays a big responsibility on the data processor. That is why we learned from our experts that the focus should be on compliance right from the start. It is always easier to do something right from the start than having to change old processes in a later stage. That is why we focus on creating awareness for our clients and offer guidance to legal experts that understand your business. Don't wait until you receive a complaint from your customers, make data protection your priority now! If you need help with **legal issues such as the GDPR or Intellectual Property**, just reach out to us by registering **here**.

The regulatory consulting service is dealing with highly complex topics. In our opinion, manufacturers of digital health technologies need to carefully consider whether their technology is a medical device and if so how it has to be classified and what steps have to be taken to get the CE mark. We realized during the last two years that this can be a difficult endeavor as many standards, guidelines and regulations are involved. Manufacturers have to stay focused on the topic, have to contemplate their product from another angle - and have to spend money. All of this can slow down the process of CE certification which in the end slows down marketing. One interesting aspect we learned from our experts is the idea to first focus on a product version which allows to launch a first product without CE certification and later on certify the product with extra functionalities. This might be an interesting option also for other SMEs. **So, if you need help with medical device related questions, please register here.**

info@ehealth-hub.eu
www.ehealth-hub.eu