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DEVELOPMENT OF A FREE WEB APPLICATION FOR CLASSIFICATION AND CE MARKING OBTENTION FOR A MEDICAL DEVICE IN EUROPE LAWS

AUTHOR: ANDIMA BEITIA VIVANCO

SUPERVISOR: JESÚS ORTÍ ESTIGUIN

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RESUMEN

Con los avances en medicina y tecnología realizados en las últimas décadas, aparecen nuevos métodos de diagnóstico, monitorización y tratamiento. Al mismo tiempo, una de las mayores preocupaciones de las autoridades y gobiernos, ha sido la seguridad y la salud de sus ciudadanos. Este proyecto recoge la regulación de las tecnologías sanitarias en el mercado europeo mediante las directivas de la Unión Europea. Tras estudiar dichas directivas y los pasos a seguir para la obtención del marcado CE, el cual permite la libre circulación del producto en el Espacio Económico Europeo, se observa que uno de los pasos cruciales es la clasificación del producto según las propias directivas, puesto que este acto marca las pautas a seguir en adelante.

Considerando la clasificación de tal manera, se propone la creación de un portal web mediante el cual realizar la clasificación de producto de una manera sencilla y eficaz. En el documento se recogen las pautas a seguir para la creación de la web desde el lenguaje de programación utilizado hasta la verificación y testeo del propio portal online. A la web mencionada se accede a través de cualquier dispositivo electrónico con acceso a internet introduciendo la dirección *"www.medical-cemarking.com".*

Además, se han escrito los términos y condiciones de uso que tanto el usuario como el propietario del sitio web deben cumplir, así como se han estudiado las leyes que se aplican a la creación del sitio web.

Por último, recoge una estimación del presupuesto necesario para realizar el proyecto teniendo en consideración tanto la labor humana como el material y licencias necesarias.

Palabras clave: Marcado CE; 93/42/CEE; 98/79/CE; 90/385/CEE; Diseño Web; Producto sanitario.

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RESUM

Amb els avanços en medicina i tecnologia realitzats en les últimes dècades, apareixen nous mètodes de diagnòstic, monitorització i tractament. Al mateix temps, una de les majors preocupacions de les autoritats i governs, ha sigut la seguretat i la salut dels seus ciutadans. Este projecte arreplega la regulació de les tecnologies sanitàries en el mercat europeu per mitjà de les directives de la Unió Europea. Després d'estudiar dites directives i els passos que s'ha de seguir per a l'obtenció del marcat CE, el qual permet la lliure circulació del producte en l'Espai Econòmic Europeu, s'observa que un dels passos crucials és la classificació del producte segons les pròpies directives, ja que este acte marca les pautes que s'ha de seguir d'ara en avant.

Considerant la classificació de tal manera, es proposa la creació d'un portal web per mitjà del qual realitzar la classificació de producte d'una manera senzilla i eficaç. En el document s'arrepleguen les pautes que s'ha de seguir per a la creació de la web des del llenguatge de programació utilitzat fins a la verificació i testeo del propi portal online. A la web mencionada s'accedeix a través de qualsevol dispositiu electrònic amb accés a internet introduint la direcció *"www.medical-cemarking.com".*

A més, s'han escrit els termes i condicions d'ús que tant l'usuari com el propietari del lloc web han de complir, així com s'han estudiat les lleis que s'apliquen a la creació del lloc web.

Finalment, arreplega una estimació del pressupost necessari per a realitzar el projecte tenint en consideració tant la labor humana com el material i llicències necessàries.

Paraules clau: Marcat CE; 93/42/CEE; 98/79/CE; 90/385/CEE; Disseny Web; Producte sanitari.

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ABSTRACT

As medicine and technology have improved in the las decades, new diagnose, treatment and monitoring methods have appeared. Meanwhile, one of the strongest worries of authorities and governments has always been the regulation of safety and security of the inhabitants of their countries. This dissertation collates information about the regulation of the medical technologies within the European market by means of the European Union directives. Once the directives and the steps that have to be followed for CE Marking, which allows the free circulation of the product in the European Economic Area, obtention have been studied, it is concluded that one of the critical steps for the obtention of the marking is the classification of the product consideration the EU directives.

Considering the classification in such a way, the creation of a web portal through which to conduct the product classification in a simple and effective way has been proposed. The document includes the guidelines to be followed for the creation of the web from the programming language used up to the verification and testing of the online portal itself. The aforementioned website is accessed through any electronic device with internet access by entering the address "www.medical-cemarking.com".

Besides, the terms and conditions that both user and owner of the website have to obey have been written, as well as the laws that apply to website creation studied.

Finally, it includes an estimate of the budget necessary to carry out the project, taking into consideration both the human work and the material and necessary licenses.

Key words: CE Marking; 93/42/CEE; 98/79/CE; 90/385/CEE; Web design; Medical Device.

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I. REPORT

I. REPORT

1. Object of study

As medicine and technology improves, new treatment and diagnose methods appear and, therefore, new devices. Already at "The treaty on the functioning of the European Union" in 1957 mention at the article 168 the need of "high standards of quality and safety for medicinal products and devices for medical use" (Bernadotte, et al., 1957). Since then, the regulation of the medical devices has experienced different changes. Nowadays, the 93/42/CEE Council Decree is used to regulate the medical device industry regarding the safety of the patient and users.

This master dissertation studies the mentioned European Union Directive and the procedures to apply it when trying to commercialize a new medical product. Those procedures are analysed and an effective method will be purposed as a solution to accelerate the bureaucratic process.

By means of a programming language software, a script will be created. A webpage will be developed in html language and the script integrated into the webpage to create a functional website to classify medical devices and obtain personalized information of the procedure to commercialize the product.

A domain and a hosting will be acquired for the created website in order to make it accessible from any device with internet connection. Tests will be done to guarantee the proper functioning of both the webpage and classification method.

All the results and knowledge gained throughout the process will be summarized and gathered to conclude the dissertation.

2. Literature review

This chapter includes a discussion of the prior work done in the field of medical device regulations and legislation. The hierarchy of the regulations must be analysed with the objective of understanding the legislation process and identify which rules need to be followed. The regulation for medical devices in Europe and, specifically, in Spain have been analysed within this dissertation.

2.1. History of medical device regulations in Europe

To understand the European regulation, some historical background is needed. When World War II ended, France and the United Kingdom signed the Treaty of Dunkirk in 1947 in order to protect themselves from possible German attacks. This treaty would be the predecessor of a union between European states. In 1951, Belgium, France, Italy, Luxembourg, Netherlands and West Germany signed the Treaty of Paris, creating the European Coal and Steel Community (also known as ECSC), considered one of the institutional creators of the European Union (from now on, EU) by some authors, together with the European Atomic Energy Community (also known as EURATOM) created in 1957 (Dedman, 1996). Both of them joined the European Economic Community (from now on, EEC and also known as European Communities or EC) created at the Treaty of Rome in 1957 by Belgium, France, Netherlands, Italy, Luxembourg and West Germany. On 1973, first enlargement took place as Denmark, Ireland and the United Kingdom joined the EU, clearing the path for Greece (1981) and Spain and Portugal (1986).

In 1986, the Single European Act (also known as SEA) was signed, considered the first major revision of the Treaty of Rome. The SEA established a deadline for a single market between the members of the EU by 1993, with the basis of free movement of goods, people, services and money. Meanwhile, in 1992, the Treaty of Maastricht was signed by all the state members (12 at that time), considered the one of the treaties that form the constitutional basis of EU along with the Treaty of Rome (European Union Website, 2017).

When studying the medical device regulation in Europe throughout history, it is important to understand the dispute between the free movement rule made as an industrial policy and the national health competencies (Permanand & Mossialos, 2005). This dispute is complicated due to the fact that it takes place against the background of the limited public health support that the EU ensures.

Medical device industry is needed for the delivery and restoration of health and well-being and to avoid premature dead, as well as innovation and research help. However, these devices can generate grave risks for human health if poorly regulated or unsuitably used. Therefore, the regulation does not aim to promote international trade but to serve public health meeting safety, quality and efficacy needs. This duel between EU rules in favour of trade and competition and the rationale of national health protection combines another contradiction, due to the increase of non-tariff barriers between 1981 and 1986 by 24% in the EU, which is believed to occur due to inconsistent national product requirements (Hanson, 2005). These non-tariff barriers restrict the import and export of goods through different mechanisms other than the imposition of tariffs. Precisely, in spite of the regulatory reforms made by the EU through recognition of technical standards and testing procedures and the release of the European market restrictions since 1980, the trend in national product regulation for medical devices has increased since mid-1980's (Joerges & Vos, 1999). Therefore, any member state which requires a higher public health standard in any new legislation has to notify the Commission about the decision mandatorily, primarily when it runs against the EU stipulations. When talking about medical devices, the notification concerns conformity assessment with essential requirements (from now on, ER) or with standards stipulated in ER (Cutler, 1998).

These individual national requirements were intended to be phased out by 1992 with the launch of the single market project in 1986 by means of the Single European Act, also known as SEA. Many authors state that neither the approximation or mutual recognition provided by the SEA work satisfactorily (Amstrong, 2002) (Hanson, 2005) (Pelkmans, et al., 2000). Therefore, a different approach was considered, where regularization through harmonization and standardization is dual. On the one hand, development of modules that specify requirements for design, quality, manufacturing processes, etcetera based on international standards, which were done by the International Organization of Standardization (from now on, ISO). On the other hand, private certification authorities were created, which certify the conformity of every product in line with EU regulatory requirements, considering the documentation and the self-declaration of conformity that needs to be submitted by the manufacturer. These authorities were called notified bodies (from now on, NO).

However, this approach did not work for medical device industry as it did for other industries. Medical device industries face extremely sensitive and confidential issues such as patient information and clinical data, information about innovation and research, intellectual property issues, etcetera. Moreover, this approach concerns industrial manufacturing data and clinical trials data, which is considered trade secret or commercial secret by a number of companies. Therefore, when the NO

needed information to support the submitted documentation, they found a high resistance due to the scepticism of the manufacturers. Related to conformity assessment, according to some authors, there was a great range about the requirements from nothing to self-declaration of conformity, to a third party reviewing the design and certifying the manufacturing processes (Hanson, 2005).

According to different authors (Hanson, 2005) (Egan, 2001), the techniques available to restrict the impact of product standards and conformity assessment requirements were not appropriate and the national protectionism eroded the EU politics. Therefore, the EU decentralized the regularization and national governments were given a major responsibility.

The new approach consisted on the basis of product safety that the EU stated, but with a decentralized implementation, which was responsibility of the home country control. This subsidiarity implies majorly two conditions. First, the EU policy for the implementation of the regulations relies on the capacity of each state member and its public or private structures, such as national government agencies, standard developing organizations commercial auditing and certification companies, etcetera. Second, that the workload of regulation is placed on manufacturers and health facilities to adapt to new legal principles. Thus, EU law, likewise the national law, does not secure implementation in the member states, which is mediated by the institutional arrangements. However, stakeholders with high influence might be involved in law implementation, not determining the final outcome. This creates a high variable conditions between the EU member states, even more in a less researched policy domain as the medical device sector (Héritier, et al., 1996).

In the full knowledge of that, the medical device industry regulations have been divided in different pathways. The first EU directive made comprehended the active implantable medical device pathway (from now on, AIMD), made the 20th of June of 1990 under the name of 90/385/CEE. Later, the medical device directive was created the 14th of June of 1993 under the name of 93/42/CEE. Both directives have been modified at the 2007/47/CE directive made the 5th of September of 2007. Lastly, the in vitro diagnostic devices (from now on IVDD) were regulated the 27th of October of 1998 by the 98/79/CE directive. Moreover, in 2005, the EU commission proposed to create a directive to regulate the support-cell and tissue-based therapies. This regulation was officially created the 13th of November of 2007 under the name of Regulation No 1394/2007. The last regulation of the four of them aims to create an integrated and tailored EU regulation for advanced therapies, which include all gene, cell or tissue therapies, and complete the framework of medical devices with specific characteristics. These different regulations and other rules were made to extol the EU regulatory capacity and avoid discrepant national approaches as the implementation lies with the national institutions.

Dissimilar to the approach of the first three directives above mentioned, the EU commission has suffered a change in the way of thinking about the forth one and is now pursuing a new approach with a centralized authorization procedure. A new expert committee within the EMEA region is about to be created in order to develop specific technical requirements adapted to the characteristics of these products, to fortify the requirements for risk management and traceability and, lastly, to provide incentives for small and medium companies. These measures move the regulation in the pathway of the pharmaceutical regime as it was done with IVDD Directive in 1998. The key issue was whether medical device regulation should be added to pharmaceutical regulatory or a distinct regulation must be done, which created a disagreement between the EU commission, national regulators, state members and representatives of both industries (Altenstetter & Permanand, 2006).

2.2. History of medical device regulations in Spain

In order to study the medical devices and public health regulation in Spain, some background needs to be done. Spain became part of the EEC in 1986 by a treaty signed the 12th of June of 1985 and, since then, it had to fulfil the policies of the EU (Pagés, 2005). However, the medical device market has not been unregulated.

The medical issues have always been a concern for Spanish power structure, from ancient times where city ramparts were closed to control epidemic diseases to the creation of laws concerning health. In the XV century, the "Real Tribunal de Protomedicato" was created to control course of medical professionals and teach and train them (Lopez Terrada & Matínez Vidal, 1996). At the early stage of the XIX century, the Balmis Expedition took place in order to enable the access of the smallpox vaccine to everyone in the Spanish Imperium, considered the first public health endeavour in the history (Balaguer Perigüell & Ballester Añon, 2003). Later in 1855 a law was created ("Ley de 28 de Noviembre de 1855) decreeing the basis of the General Health System and regulating, for the first time, medicine and vaccines as well as empowering some people to control the maritime and inland borders according to medical issues (Unknown, 2010). The Spanish government created in 1908 the Spanish national Health System by employing the Royal Decree of the 12th of January of 1904. In 1934, the Sanitary Coordination Law was created with the objective of centralising the local health systems and suggest the creation of Health Ministry. However, the Civil War started and the law was not accomplished.

After the Civil War an under the dictatorship of Francisco Franco, the Compulsory Disease Insurance was created by the Law of the 14th of December of 1942, which will later be restructured into the General Social Security Law on 1975 (BOE, 1974). Due to the adhesion of Spain as a member state of EU in 1986 and the creation of the Spanish Constitution in 1978, a new approach had to be made to fulfil the requisites. Therefore, the General Health Service Law was made the 25th of April of 1986 as well as the creation of Health Service offices and its own Health Ministry. This law, at the 40th article, specifically in sections 5 and 6, confer competency to regulate, consent and register every human or veterinary use medicine or device to the General State Administration (BOE, 1986).

From then on, as part of the EU and within the SEA which followed a single European market, the medical device industry regulation was under the EU policy. Nevertheless, as previously mentioned, being part of the EU did not compulsorily suppose a change in the state administrative method. However, in order to fulfil the EU policy in medical device regulation, the previously mentioned AIMD, IVDD and medical device directives, 90/385/CEE, 98/79/CE and 93/42/CEE respectively, needed a transcription in Spanish administrative method. Each member state of the EU needed to accomplish some basis that the EU commission decided but, if it was considered that more restrictive regulation was needed to ensure the safety of the users and patients, they were allowed. Thus, the AIMD directive was transcribed into the Royal Decree 634/1993 published on the Official State Bulletin the 3rd of May (BOE, 2009). The medical device directive was transcribed into the Royal Decree 414/1996 published in the Official State Bulletin the 1st of March (BOE, 2009). Lastly, the IVDD directive was transcribed into the Royal Decree 1662/2000 published in the Official State Bulletin the 29th of September (BOE, 2000). The AIMD and the medical device Royal Decrees have suffered changes since then and new versions have aroused, the Royal Decree 1143/2007 and the Royal Decree 1616/2009 modifying the first of them and the Royal Decree 1591/2009 the modifying second one.

3. Justification

This chapter includes a discussion of the technical and academic content that the dissertation will follow. The project must be both technically and academically justifiable and viable in order to be accepted as a Master Dissertation project.

3.1. Technical justification

As previously explained, the project consists on the development of a free web for medical device classification from the CE Marking obtention point of view. Moreover, a review of the actual European regulation of medical devices has been done in order to thoroughly understand the applicable regulation in the field.

Regarding the web design, technical skills are needed. Different tasks are to be done within the process to obtain a functional web. Moreover, design skills are advisable to create an attractive and easy website, understandable for a wide range of users with different technical skills. On the one hand, programming skills have been acquired by the creation of the webpage in HyperText Markup Language (from now on, HTML) and Cascading Style Sheets (from now on, CSS) languages. The source code of the website has been engineered form scratch by means of “Brackets” software, a programming software for HTML and CSS.

On the other hand, computer knowledge has been needed to make the webpage available from any device by purchasing a domain and a hosting. Once both have been obtained, the HTML and CSS documents created can be uploaded into de purchased hosting and viewed from any device with internet connection. Computer skills are needed to manage the hosting options, databases, servers used, file transfer protocols and diverse technical issues that might arise during the process of the website creation.

Lastly, regarding the medical device regulation, a method has been created to classify the product in a fast manner. By this method, time is saved when classification needs to be done due to the suppression of the regulation analysis by the user of the website. The user answers the questions that appear in the website and the product is classified itself by following a previously design flowchart. Moreover, once classified, the next steps of the process appear in the website guiding the user in the correct procedure for CE Marking obtaining.

3.2. Academic justification

As regards the academic section of this dissertation, the project is divided in two areas. First, as explained in the previous section, the programming area. Second, the regulatory and legislative area. Both of the sections contribute into the academical growth by improving the skills and knowledge of different subjects studied throughout the Master degree.

The medical device market regulation has been widely studied during the academic year. By means of this Master dissertation, the regulations studied have been meticulously analysed and understood in order to provide a correct pathway for the users to obtain the CE Marking of their product. Moreover, by means of this dissertation, different standards have been studied, expanding the understanding and knowledge of the standards that apply to the medical device industry.

Besides, regarding the programming of the website, new skills have been gained throughout the project. An unknown language (HTML and CSS) and software (Brackets and PHP-Eclipse Mars) have been used for the execution of the dissertation, improving the programming language by providing different approaches and solutions when software design is needed.

4. Scope and development of Master Dissertation

The project comprises the steps from analysing and studying the European Directives relative to medical devices to produce a method for an easy classification of the products and apply it to a website. The current regulation has been studied and just European Directives have been considered for the project. In consideration of that, the above-mentioned Regulation No 1394/2007 for support-cell and tissue-based therapies has not been considered. Throughout the project, a wide variety of phases have been covered.

4.1. Analysis of European Decrees

The analysis of regulation stage is divided in different sections, each section covering one of the three European Directives analysed in the project.

On the one hand, the 90/385/CEE EU directive for AIMD, has been studied. The different group of devices have been distinguished and its related procedure emphasised. On the other hand, the 93/42/CEE directive for medical devices has been analysed, where the main classification method has been studied. Lastly, the 98/79/CE directive for IVDD has been studied, paying attention to the different groups stated in second annex. Moreover, the Spanish transcriptions into Royal Decrees have been studied to outline any possible differences.

During this step, special attention has been paid to the classification method stated in the directives due to the main objective of the project, the creation of a medical device classification website.

4.2. Creation of flowcharts and classification methods

Once the EU directives have been studied and the classification method analysed and understood, flowcharts had to be done. The distinguishing factors of the groups and classification rules have been expounded creating an excel table.

Taking into consideration the table created and the data extracted form the directives, a flowchart has been created. This flowchart classifies the medical device by asking different double choice questions as in a decision tree. The developed flowcharts have been analysed to notice possible corrections and improvements, such as changing the order of some questions to shorten the process.

4.3. Creation of website

This step consists on the creation of a website from scratch. By diverse programming languages and by purchasing a domain and an external hosting, a website has been created. This website includes the above-mentioned flowcharts, making it possible to classify different products. Moreover, once classified, it provides information about the next steps that the user should take to obtain the CE Marking and commercialise the product. Lastly, it contains some definitions from the directives, providing the user a correct understanding of every question.

4.4. Verification and testing of method

After the website has been created both aesthetically and in a functional manner, some testing has been done. This step verifies that the website operates correctly and that the classification of the product is correct and precise.

For the first task, the verification has consisted on checking that every button and tab open the expected information. Moreover, the website has been verified in diverse electronic devices to confirm that the web works both in computer and smartphones.

Whereas, for the second task, different medical devices with a known classification have been selected as test devices. The system has been checked by answering the classification tab questions taking into consideration the previously mentioned testing devices. By comparing the result and the known classification, the performance of the website has been analysed.

4.5. Completion of the report

The report has been written up alongside all the previously stated tasks. The report should be finished a few days before the deadline keeping a margin in case any error occurs and the scheduled ending is delayed.

5. Fundamental basis of the system

When obtaining the CE Marking of a medical device, one of the most critical steps is the classification of the product. An incorrect classification might produce a non-conformity of the assigned NO or even a recall from the market, if the product is already commercialised. Both actions result in a financial loss of the manufacturer as time and money is invested in product regulation and medical field technologies. When a product is found to not be in full compliance with the regulation, a wide range of consequences appear. These consequences could be, but are not limited to:

- Removal of product from the market temporarily or permanently.
- Refusal of free movement of the product in EU zone.
- Restarting of the compliance process.
- Loss of CE Marking.
- Recall of the product form users.
- Ban on the marketing of the product.
- Destruction of the product.

As some authors state, a product recall or any sort of problem in sensitive markets for humans as medical device industries, pharmaceutical industry or food industry, produces a significant shareholder and consumer loss (McKenzie, 2001) (Rohini Ahluwalia, 2000). Therefore, a correct classification of the device would prevent different issues associated to the firm reputation and economy.

Thus, through the development of the project, both a correct classification and a reduction in needed time has been sought by the development of an online platform. The system has been developed based on the EU directives regarding medical devices, AIMD and IVDD. Having studied the classification method stated in those directives and having identified the differentiating factors of each group, a

decision tree-like flowchart has been created. Each ramification of the flowchart has been created by a two-fold answer question, where yes or no is the only answer. After a set of questions, the riskness degree classification is obtained by reaching one of the multiple ends of the flowchart.

Firstly, it has been decided that the three different product groups should be divided to analyse each directive individually. Therefore, the first question divides the devices into IVDD products and the rest of them. If the product belongs to the IVDD family, if the "A" or "B" lists at the EU 98/79/CE directive applies to the product has been found and, in case it does not, if the product is designed for a self-diagnose. Secondly, the AIMD and general medical devices have been divided. If the product belongs to AIMD, different pathways appear if it is custom-fitted or not. Lastly, the general medical devices have been analysed and classifies following the annex IX on the EU 93/42/CEE directive. The flowchart for general medical devices has been thoroughly explained hereinafter.

Once the classification has been completed through the mentioned flowchart, the CE Marking obtention pathway has been studied according to the applicable directive. Thus, the online platform informs the user the different options to obtain the CE Marking by redirecting him or her to the required and mandatory annexes of the corresponding EU directive.

6. Legislative context

As exposed in a previous section, the EU policy about the safety of the commercialised products has suffered numerous changes in recent years. The medical device market is a recent and unexplored one compared to others such as food or commonly used product market. As medicine and technology improves, new treatment and diagnose methods have appeared in the medical industry. Moreover, the manufacturing technologies have suffered a number of changes during the last 30 years, allowing a mass production and much more autonomous environment in factories. However, the surveillance of the medical devices needs to meet safety requirements both for the patients and end-users. Within that context, the EU has created three different regulations to ensure the correct functioning of the products without endangering any potential stakeholder.

First, the 98/79/CE directive, which governs the IVDD products and was created the 27th of October of 1998. This directive applies to IVDD and their accessories, as stated in the "Article 1: Scope and definitions":

> *"This Directive shall apply to in vitro diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as in vitro diagnostic medical devices in their own right."*

Within the same article, in the definitions section, the IVDD is defined as *"any device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro"*. These instruments can be used for examination of specimens and solely or mainly for obtention of information or monitoring of therapies. Notwithstanding, the specimen receptacles are also considered IVDD if the manufacturer intends its use for preservation of specimens derived from human body for examination use, as well as any other product which the manufacturer specifies an in vitro diagnose use.

As any other medical device, the essential requirements stated in *Article 3*, which can be found in annex I, are for obligatory compliance always considering the purpose of the product. Besides, before

commercialisation of the device, the conformity assessment is required. The procedure for this assessment changes depending on the classification of the product. In case of IVDD, the annex II includes two lists, list A and list B, of devices, which makes the first classification. If the product is not included in any of the lists, a differentiation is done between general products and those directed to self-diagnose and/or operation assessment.

Article 9 states the correct procedures to conduct the conformity assessment for every product type. Thus, the point 1 of the mentioned article informs the procedure for general and self-diagnose products not listed in annex II:

> *"For all devices other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex III and draw up the EC declaration of conformity required before placing the devices on the market.*
>
> *For all devices for self-testing other than those covered by Annex II and devices for performance evaluation, the manufacturer shall, prior to the drawing up of the aforementioned declaration of conformity, fulfil the supplementary requirements set out in Annex III, point 6. Instead of applying this procedure, the manufacturer may follow the procedure referred to in paragraphs 2 or 3."*

Moreover, for products listed in the A list of annex II, the second point of the article 9 states as follows:

> *"in order to affix the CE marking either:*
>
> *(a) follow the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance), or*
> *(b) follow the procedure relating to EC type-examination set out in Annex V coupled with the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance)."*

For those products in the B list of the annex, the third point of the article states:

> *"for the purposes of affixing the CE marking, follow either:*
>
> *(a) the procedure relating to the EC declaration of conformity set out in Annex IV (full quality assurance) or*
> *(b) the procedure relating to EC type-examination set out in Annex V couplet with:*
> *(i) the procedure relating to EC verification set out in Annex VI, or*
> *(ii) the procedure relating to the EC declaration of conformity set out in Annex VII (production quality assurance)."*

Lastly, for those products which the manufacturer specify that have an operating assessment objective, the 98/79/CE directive in its article 9, point 4, states as follows:

> *"In the case of devices for performance evaluation, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before such devices are made available."*

Besides, before the product is commercialised, the manufacturer shall inform the authorities of the member state in which it is registered diverse information about the company itself such as the address of the registered business place. Some information about the device is also required, such as the reagents, reagent products and calibration and control materials of the technology, as well as any change in the information provided previously. Moreover, if the device is covered by the annex II and/or it is considered self-testing, *"all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Annex I, part A, section 3, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto, including discontinuation of placing on the market"* must be notified according to the article 10, point 1, section 3 of the IVDD directive.

Regarding the 90/385/CEE EU directive of the 20th of June of 1990 concerning AIMD products, active implant medical device shall be construed as the article 1, point 2, section c states:

> *"any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;"*

Nevertheless, the directive applies to custom-made active implantable devices and active implantable devices intended for clinical investigations too, as states the article 3 of the mentioned directive. All these products have to fulfil the essential requirements stated at the annex I, considering the final application of the device.

As in the previous analysed directive, the article 9 specifies the correct procedure for the CE Marking obtention. The classification in this case is not needed as the three groups are significantly different and general AIMD devices are considered high risk as a whole. In the case of the custom-made AIMD products, the manufacturer has to complete the annex IV as stated in the point 2 of the article 9. however, the CE Marking for AIMD general products shall be obtained as stated in article 9, point 1:

> *"[…] to affix the CE mark, at his own choice:*
>
> *(a) follow the procedure relating to the EC declaration of conformity set out in Annex 2; or*
> *(b) follow the procedure relating to EC type-examination set out in Annex 3, coupled with:*
> *(i) the procedure relating to EC verification set out in Annex 4, or*
> *(ii) the procedure relating to the EC declaration of conformity to type set out in Annex 5."*

Besides, for products intended for clinical investigations, the article 10 states that the manufacturer should notify the competent authorities at least 60 days before the investigations are to be conducted, as well as submit the statement referred to the annex IV to those authorities. Once submitted, the investigations can be conducted 60 days after the submission, unless the authorities have notified a contrary decision within that period.

Lastly, the CE marking is only required for the general AIMD general products, being the custom-made devices and those intended for clinical investigations exempt of bearing the CE marking, as article 12, point 1 state:

"Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the EC mark of conformity."

Finally, the 93/42/CEE EU directive of the 14th of June of 1993, by which the medical devices and their accessories are regulated has been analysed. This directive, in its article 1, point 2, section a, defines medical device as:

"'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software 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 compensation 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;"

Moreover, in the section c, defines accessory as any which is not considered medical device by the previous definition but it is intended specifically by the manufacturer to be used together with a medical device to guarantee the conformity and correct functioning of the device.

As in the previous directives, the article 2 mentions that all products must fulfil the essential requirements in annex I:

"The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned."

Medical devices, unlike the IVDD or AIMD products are classified in 4 different groups according to the risk produced. Article 9, point 1, states that all the products are required to be classified into I, IIa, IIb or III groups, being the manufacturer the responsible of this task by applying the annex IX rules. However, in the case of a misunderstanding between the NO and manufacturer regarding the classification, the decision shall be taken by the competent authorities, as stated in the point 2 of the same article:

"1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject."

Therefore, when classifying general medical devices, which are not custom-made nor intended for clinical investigations, annex IX has to bee applied, specifically its chapter III, classification criteria. The classification method consists on 18 rules which cover all the medical device spectrum. These rules are divided in blocks for non-invasive products (4 rules), invasive devices (4 rules), rules applicable to active devices (4 rules) and special rules (6 rules). The outcome of applying these rules to our product is a

class I, IIa. IIb or III classified product, being class I the less risky and class III the most. Depending on the class, one or another process has to be followed for the conformity assessment. Thus, as stated in article 11, point 1, the class III products shall:

"In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or
(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:
(i) the procedure relating to the EC verification set out in Annex IV; or
(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance)."

Moreover, for those products falling in the class IIb, the article 11, point 3 states as follows:

"in order to affix the CE marking, either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or
(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:
(i) the procedure relating to the EC verification set out in Annex IV; or
(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or
(iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance)"

Regarding the medical devices that are considered as class IIa products, the EU directives states in its article 11, point 2 as follows:

"in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either:

(a) the procedure relating to the EC verification set out in Annex IV; or
(b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or
(c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance)."

Lastly, the point 5 of the above-mentioned article specifies the procedure of the class I products for the CE Marking obtaining:

"In the case of devices falling within Class I […] follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market."

Point 6 of the article 11 mention that custom-made products shall obey the annex VIII for the commercialisation of the products. However, more documentation might be required depending on the classification of the product, as the operating license, for example.

7. Proposed solution

Within this chapter, the proposed solution of the project has been discussed, considering all aspects of the project and analysing different possibilities.

7.1. Legislation and classification mechanisms analysis

As mentioned in the previous chapter, legislative context, there are three different EU directives that apply to the medical devices, depending on the characteristics and intended use of the device. Thus, the device regulation is solid and safety requirements need to be fulfilled before commercialisation. The project has been conducted in Spain, however, the European regulatory framework has been chosen to perform the project. As above mentioned, the EU policy is to empower the state members by allowing more restrictive transcriptions of the directives proposed by the EU Council. Thus, the regulation of a product in different state members might be slightly different, providing always the safety and security, as well as effectiveness, of the product to the end users. To conduct this project, the main EU Council directives have been chosen. The main reason of creating an online platform is to reach as most people as possible. Therefore, if a national law or regulation document is utilised to perform the basis of the web, it might not be useful for international users. Hence, as the basic EU directives are mandatory and equal to every state member, users from different countries are equally represented.

Meanwhile, the classification mechanism of each directive has been studied in previous sections. Different solutions have been considered. On the one hand, creating a tab for each directive has been evaluated. This solution simplifies the basic system by analysing each directive individually isolated. However, the user might not know which directive applies and the source code would be complicated. On the other hand, joining all the regulations in one when classifying has been considered and chosen as the best option. By doing this, users experience has been made in a simple and attractive manner, as even a user with no knowledge of the industry would be able to classify the product.

7.2. Flow chart development

Once the regulation framework and classification method have been chosen, a flowchart has been made to create an overview of the whole classification system. With the objective of identifying the differentiating factors of the classification rules, an Excel table has been created. Outrightly identified those factors, two different option arise for the flux diagram.

On the hand, a multiple-choice question method has been considered. This method would create a decision-tree-like diagram. However, this method has both benefits and drawbacks. A decision-tree-like diagram would be easier and faster to design the online portal, and the classification would be quick. Nevertheless, the user should have a better understanding of the regulations that apply.

On the other hand, a yes-no question method has been thought. This method encounters pros and contras as well, as the design and creation of the website becomes more difficult and more time is

needed. Conversely, the user will have a complete understanding as the questions must be simple and concise.

Taking into consideration both methods and analysing them, a yes-no question method has been chosen to create the flux-diagram of the classification system.

7.3. Software and programming language

Regarding the software and programming of the online portal, a wide variety of options have appeared. Currently, multiple programming languages are available. However, HTML language is considered the basis of web programming, even if it is not considered a programming language but a markup language. HTML works by encapsulation of data, which describes and defines the data and its purpose on the web. As Figure 1 shows, the text is encoded in tags such as “title”, “h1” or “p” and each tab have a purposed, which is translate by the web browser into the style of the writing. For the completion of the project, HTML has been used as it is a proven language which provides a wide variety of options.

Figure 1:Example of HTML language and results.

Besides, the HTML style by itself is simple and archaic, therefore, a CSS has been created all at once. The CSS language is widely used in HTML documents to give them a visual attractive design online. One of the main advantages that CSS has is the easiness to change the design, as by changing a single line of the source code, a new style sheet can be displayed.

Documents in both languages have been written throughout the project in “Brackets” code editor software. This editor is license free and open source.

7.4. Webpage development

The webpage has been created from scratch by means of HTML and CSS. Yet, these are text documents in the computer which have no value until a domain and a hosting are purchased. Several companies have appeared in recent years trading with new and existing domains. A domain is an identification string which is unique for every webpage. When the domain is purchased, a hosting or web hosting service is needed to make the website accessible from the World Wide Web. Besides, some hosting

providers offer data centre space and allow uploading different documents. In this project, both domain and hosting have been purchased by OVH firm, the biggest provider of domains and hosting in Europe.

7.5. Evaluation method and tests

Once the web has been done and classification method applied into the website, testing has been done to evaluate the implementation and performance. Two different testing have been chosen: a functional test for the website as a whole, verifying that there is not any error, and a performance or effectiveness test for the classification method, verifying that the classification is correctly done.

The functional tests have been developed by the unit testing method. Unit testing is the first level of testing and is often performed by the developers themselves. It is the process of ensuring individual components of a piece of software at the code level are functional and work as they were designed to.

On the other hand, performance testing is a non-functional testing technique used to determine how an application will behave under various conditions. The goal is to test its responsiveness and stability in real user situations. In our case, the different conditions applied have been the characteristics of the product to classify.

8. Development

The project development has been divided in three phases: Analysis and flux-diagram creation, website design and implementation and testing of the website. The first phase consists on a thorough analysis of the actual classification method and the creation of the yes-no questions by means of a flux-diagram, which will be later implemented in the website. The second phase is based on the programming and writing of the source code and style sheets of the online portal, as well as its implementation in the World Wide Web. Lastly, the third phase consists on the previously mentioned testing and evaluation of the website and classification method.

8.1. Phase 1: Analysis of regulation and creation of classification flowcharts.

In the previous section “Legislative context”, the EU directives that apply to medical devices have been analysed. Within this phase, the main objective is to identify the classification system that each directive uses and create a method that ensembles all of them within a flowchart.

Firstly, the IVDD 98/79/CE directive has been studied. As stated in previous sections, IVDD devices can be divided in various groups. First of all, the existence of the A list and B list on the annex II, the first two groups have been discovered: IVDD-A or IVDD-B devices. Moreover, we can observe that, in the Article 9, point 1, the IVDD products for self-diagnose require a different procedure, therefore, we can consider those devices as a different group (self-diagnose IVDD). Besides, in the same article but in the point 4, a different group appears due to the intended use, the performance evaluation IVDD group. Lastly, the rest of devices to which this directive applies are considered another group (general IVDD). Hence, these devices are divided in 5 different groups: IVDD-A, IVDD-B, self-diagnose IVDD, general IVDD and performance evaluation IVDD. Thus, the first flux-diagram block can be created as Figure 2 shows.

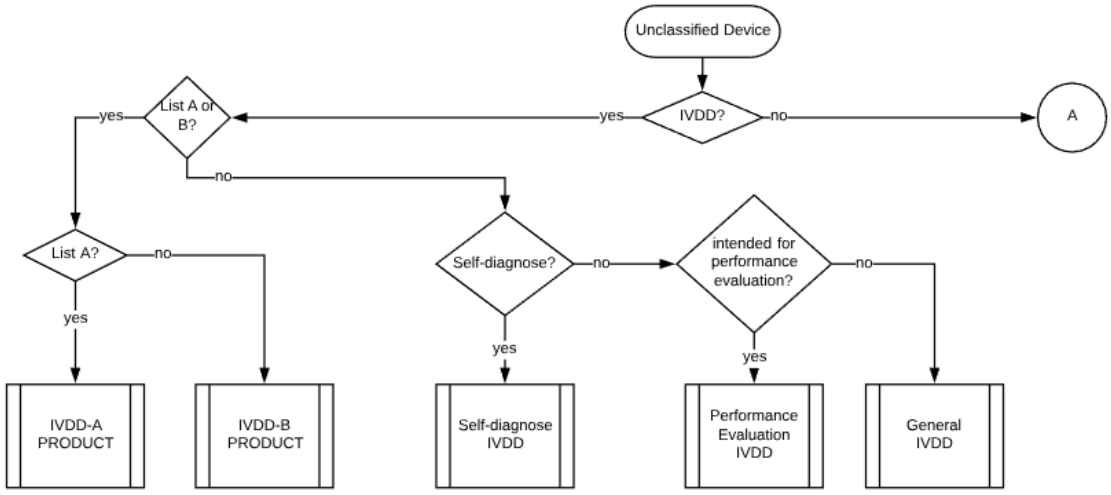

Figure 2: Provisional flux-diagram at the IVDD block.

Secondly, the AIMD directive 90/385/CEE has been analysed as in the "Legislative context". Within this framework, the AIMD directive in its Article 3 states that it is applicable for three type of AIMD products:

> *"The active implantable medical devices referred to in Article 1 (2) (c), (d) and (e), hereinafter referred to as 'devices' […]"*

Where "c", "d" and "e" are AIMD, custom-made and device intended for clinical investigation respectively. Hence, the AIMD devices are divided in three groups: general AIMD, custom-made AIMD and clinical investigation AIMD. This allows to improve the flux-diagram by adding the AIND block as Figure 3 shows.

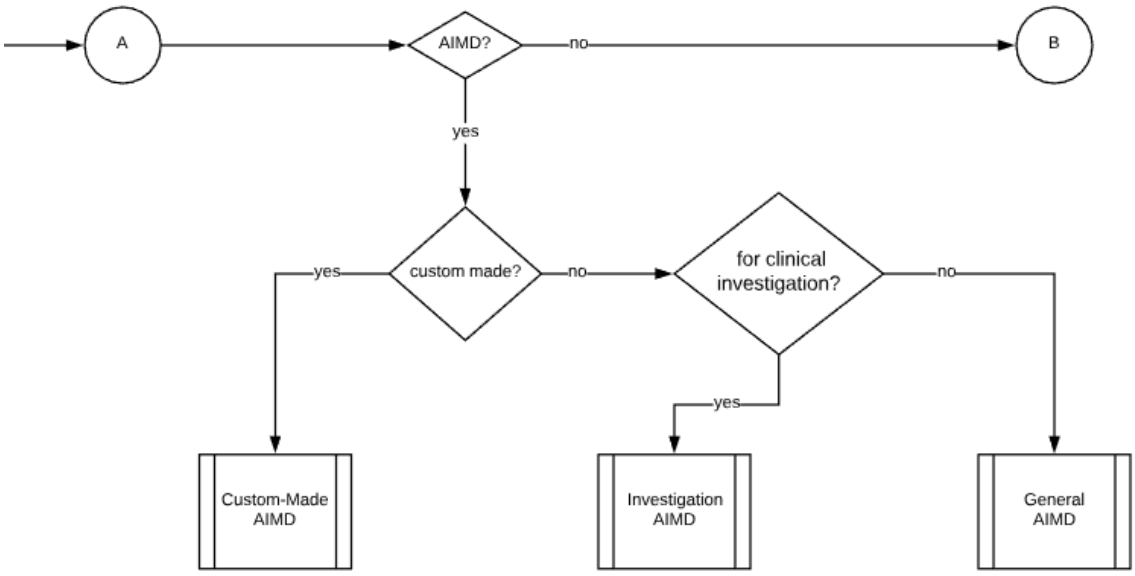

Figure 3: Provisional flux-diagram at the AIMD block

Lastly, the 93/42/CEE directive has been studied. This directive, as stated in the article 9, divides the devices *"Classes I, IIa, lib and III"*. Furthermore, custom-made medical devices are also differentiated. Therefore, 5 groups are considered: class I, class IIa, class IIb, class III and custom-made devices.

As stated in previous sections of the project, the main task within this directive has been to find the differentiating factor of the mentioned groups. The 93/42/CEE document expounds in the Article 9 that the classification should be done taking into consideration the annex IX rules. With the objective of finding those factors that distinguish between device classes different tables have been done. The rules at the annex IX are divided into four main groups: non-invasive devices, invasive devices, active devices and special rules, being invasive described as *"A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body"* in the chapter 1, point 2 of the annex IX. Different tables have been done to discover those differentiating factors. Thus, Table 1 has been done for the non-invasive devices rules, Table 2 for invasive medical devices rules, Table 3 for active medical devices rules and, lastly, Table 4 for those special rules.

Looking into those tables, the differential factors have been analysed and, later, assembled to create the most precise yes-no questions to introduce in the flux diagram. In accordance with the main four rule groups, which divided the mentioned tables as well, the flux diagram has been improved by using the differentiating factors obtained by the tables above mentioned.

By implementig the flux-diagram into the source code of the online portal, the classification has been obtained.

Group	Rule	Section	CLASS				Reason	
			Class I	Class IIa	Class IIb	Class III	General	Specific
Non Invasive	1	N/A	X				No other rules apply	Genera rule for non-invasive products
	2	2.1		X			Designed for the conduction or storage of blood / fluids / tissues / liquids / gases for perfusion / administration / introduction of these	Connects to active device
		2.2		X				Storage or channelling of blood / fluids or storage of organs
		2.3	X					Do not enter in previous groups (Channel or store liquids / gases)
	3	3.1			X		Intended to modify biological or chemical composition of blood / fluids / liquids for introduction	Modify composition of blood or fluids to introduce
		3.2		X				The modification is filtration, centrifugation or gas / heat exchange
	4	4.1	X				In contact with injured skin	Mechanical barrier for compression or absorption of exudates
		4.2			X			Mainly destined to wounds with rupture of the dermis and can only heal by secondary intention.
		4.3		X				The rest of cases included those destined to microenvironment of wounds

Table 1: Non-Invasive differential factor table.

Group	Rule	Section	CLASS				Reason	
			Class I	Class IIa	Class IIb	Class III	General	Specific
Invasive	5	5.1	X				Invasive products in relation to body orifices (except invasive surgical) that are not connected to an active product superior to Class I	Intended for short-term or transient use if it is in the oral cavity (Max pharynx), auditory (Max eardrum), nasal
		5.2		X				Short-term or long-term use if it is in the oral cavity (max pharynx), auditory (max eardrum) or nasal and is not absorbed by the mucous membranes
		5.3			X			Long-term use
		5.4		X				Connects to an active product superior to Class I
	6	6.1		X			Invasive product of surgical type for transitien use	Invasive product of surgical type for transitien use general rule
		6.2				X		Aimed at controlling, diagnosing, monitoring or correcting cardiac alteration or Central Circulatory System by direct contact.
		6.3	X					Reusable
		6.4				X		In contact with the central nervous system
		6.5			X			It supplies energy in the form of ionizing radiation
		6.6			X			Exerts biological effect or is totally / partially absorbed
		6.7			X			Administer medications in a potentially dangerous way depending on the mode of application

	7	7.1		X			Invasive surgical-type product for short-term use	General Surgical Invasive Short term
		7.2				X		controlling, diagnosing, monitoring or correcting cardiac alteration or Central Circulatory System by direct contact
		7.3				X		In contact with the central nervous system
		7.4			X			It supplies energy in the form of ionizing radiation
		7.5				X		Exerts biological effect or is totally / partially absorbed
		7.6			X			Experiment chemical modification in the body (except in teeth) or administer medication
	8	8.1			X		Invasive product type long-term use	General Surgical Invasive Long term
		8.2		X				Place inside teeth
		8.3				X		In contact with the central nervous system or central circulatory system
		8.4				X		Exerts biological effect or is totally / partially absorbed
		8.5				X		Experiment chemical modification in the body (except in teeth) or administer medication

Table 2:Invasive differential factor table

Group	Rule	Section	CLASS				Reason	
			Class I	Class IIa	Class IIb	Class III	General	Specific
Active products	9	9.1		X			Active therapeutic products intended to exchange or administer energy to the human body	General
		9.2			X			Exchanges or administers in a potentially dangerous way by nature, density or point of application
		9.3			X			Control the functioning or influence the functioning of an active therapeutic class IIb
	10	10.1		X			Active products for diagnostic purposes	It supplies energy absorbed by the human body except the illumination of the body in visible spectrum
		10.2		X				Create an image of the distribution of radioactive drugs
		10.3		X				Allows a direct diagnosis or monitoring of physiological processes or monitoring of vital parameters when it does not pose an immediate danger to the patient's life
		10.4			X			Vigilance of vital parameters when it is an immediate danger to the life of the patient
		10.5			X			Intended to emit ionizing radiation for diagnosis or therapy or products that control these or directly influence the functioning of these
	11	11.1		X			Active products destined to administer medicines, liquids or other substances or to extract them.	General
		11.2			X			Administers or extracts liquids, medicines or others in a potentially dangerous way by the substances,

								part of the body to be treated or application mode
	12	N/A	X				Does not meet any of the above rules	General rule for active medical devices

Table 3: Active differential factor table.

Group	Rule	Section	CLASS				Reason	
			Class I	Class IIa	Class IIb	Class III	General	Specific
Special rules	13	13.1				X	Products that incorporate substances	If that substance, by itself, can be considered a medicine according to Article 1 of Directive 2001/83 / EC and can exercise an accessory action on the body
		13.2				X		Substances derived from human blood as part of the product
	14	14.1			X		Contraceptive products or for prevention of Sexually Transmitted Diseases	General
		14.2				X		Are implantable or long-term products
	15	15.1			X		Products destined for disinfection, cleaning.	Cleaning, disinfecting, moisturizing or rinsing contact lenses.
		15.2		X				Disinfection of general devices
		15.3			X			Disinfection of invasive devices
	16	N/A		X			Products intended for recording diagnostic x-ray images	General
	17	N/A				X	Products made using animal tissues or derivatives that have been transformed into non-viable (Except if they are in contact with the skin ONLY)	General
	18	N/A			X		Blood bags	General

Table 4: Special rules differential factor table.

8.2. Phase 2: Creation of website and implementation

The first step to create the website, after downloading the software and deciding the programming language, has been to decide for which device to create it. There are several window sizes (computer, smartphone, tablets, etcetera), however, by making a responsive design, the HTML and CSS will automatically resize, thus, a responsive web design has been chosen. Moreover, the "UTF-8" character set has been chosen to design the portal. UTF-8 is a variable width character encoding system defined by the Unicode standard. This system can support many languages and can accommodate pages and forms in any mixture of those languages. Moreover, the HTML specification state that *"Authors should use UTF-8. Conformance checkers may advise authors against using legacy encodings. "* (unknown, 2017). Moreover, a fixed menu bar has been thought to be useful within the web portal. Thus, the head of the coding looks as in Figure 4 both in HTML and CSS.

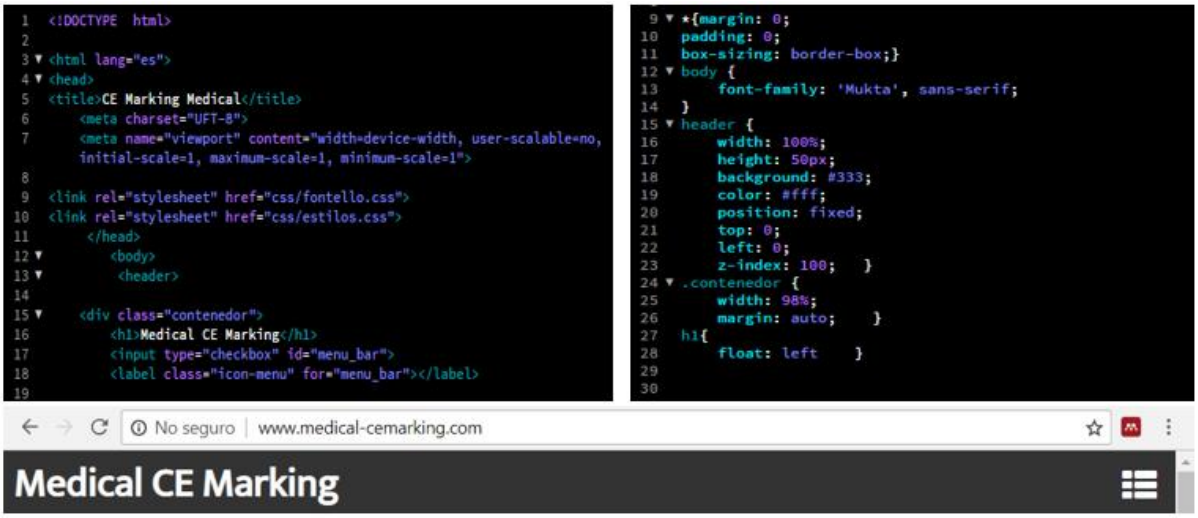

Figure 4: Head of the main document of the webpage in HTML (top-left), CSS (top-right) and result (bottom).

Websites created using responsive design are designed to display different content as the browser is expanded or reduced to predetermined sizes. For example, when the browser size is reduced to 70% of its maximum width, the webpage may have been set to display only two columns on the screen rather than three. When the browser is expanded past 70% of the screen, the third column of content will return to the screen. Figure 5 shows the results of the responsive design within this website.

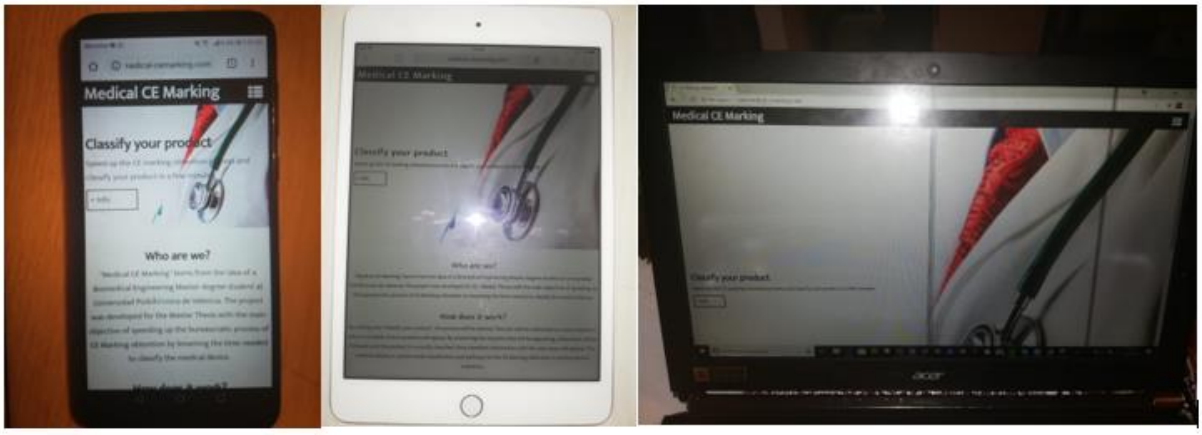

Figure 5: Responsive web in smartphone (left), iPad (middle), laptop (right).

Being the heading done, the homepage has been created. With the objective of making it attractive and reliable at the same time, some information about the objective of the website has been introduced. Moreover, an easy and simple design has been achieved by creating an intuitive menu, which is activated when clicking into the menu icon at the top-right side. Within the menu, links to all the sections on the online portal have been introduced. This menu has been designed to be displayed in every section of the website, being able to go to any section at any time. Furthermore, a banner has been created for a more visual impact on the user, who clicking on the "+ Info" button will be able to know more about the project and method used to classify. The welcome page displays as can be seen in Figure 6.

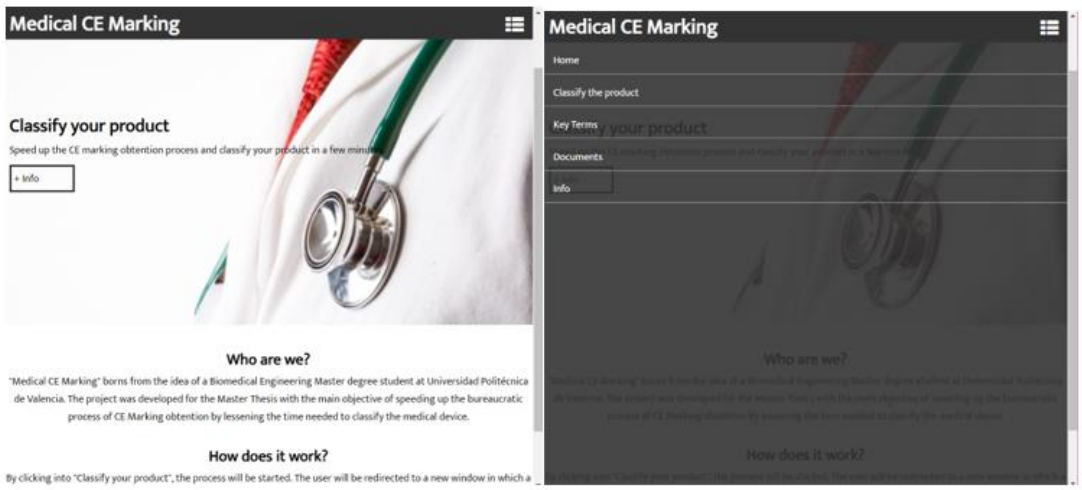

Figure 6: Welcome section (left) and opened menu bar (right)

Once the welcome and menu have been designed, the other sections have been created. This dissertation has particular emphasis in the key terms and classification sections. The first of them, the "Key Terms" section resembles a dictionary by adding explanations of those words that, beforehand, might be difficult to understand or have a specific definition. Thus, terms as "implantable", "in vitro diagnostic", "active device" and "transient" have been added. Figure 7 shows an example of some terms.

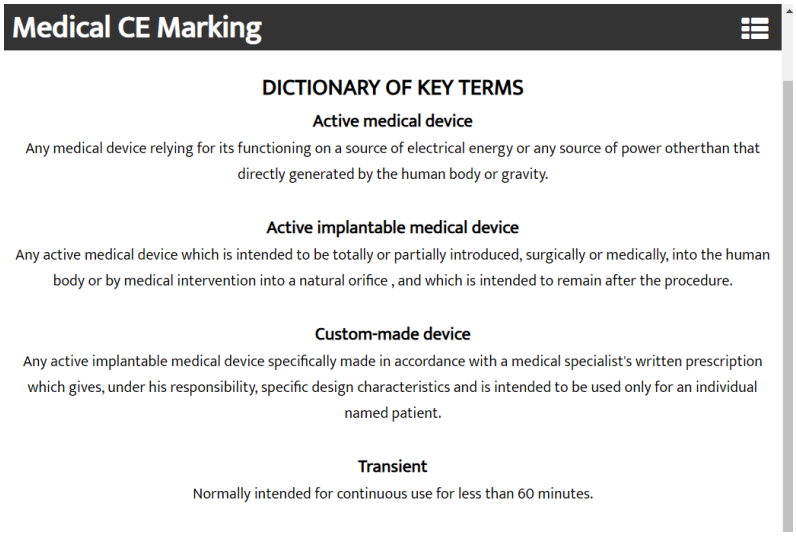

Figure 7: "Key Term" section example in the website.

Last but not least, the classification section has been done. First a main page has been displayed, where the step-by-step procedure has been explained, as well as the first question displayed, as can be seen in Figure 8. Once the question has been answered, taking into consideration the possibility of consulting the *"Key Terms"* section for a better understanding by opening it in a new tab, *"Next"* button in the bottom part of the image needs to be clicked. When so is done, the website has been programmed to show the next question of the flowchart. There is a possibility to quit the classification by clicking in *"End"* button. If so, the website will be redirected to another section where the next steps of the procedure for CE Marking obtention are showed depending on the class of your product, which can be seen in Figure 9.

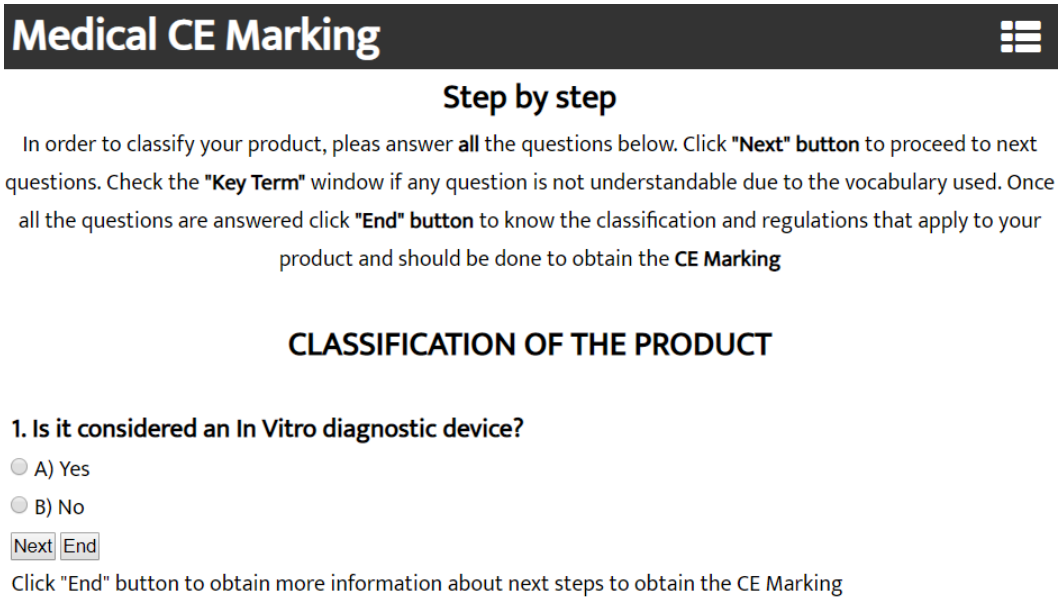

Figure 8: Classification section of the online portal.

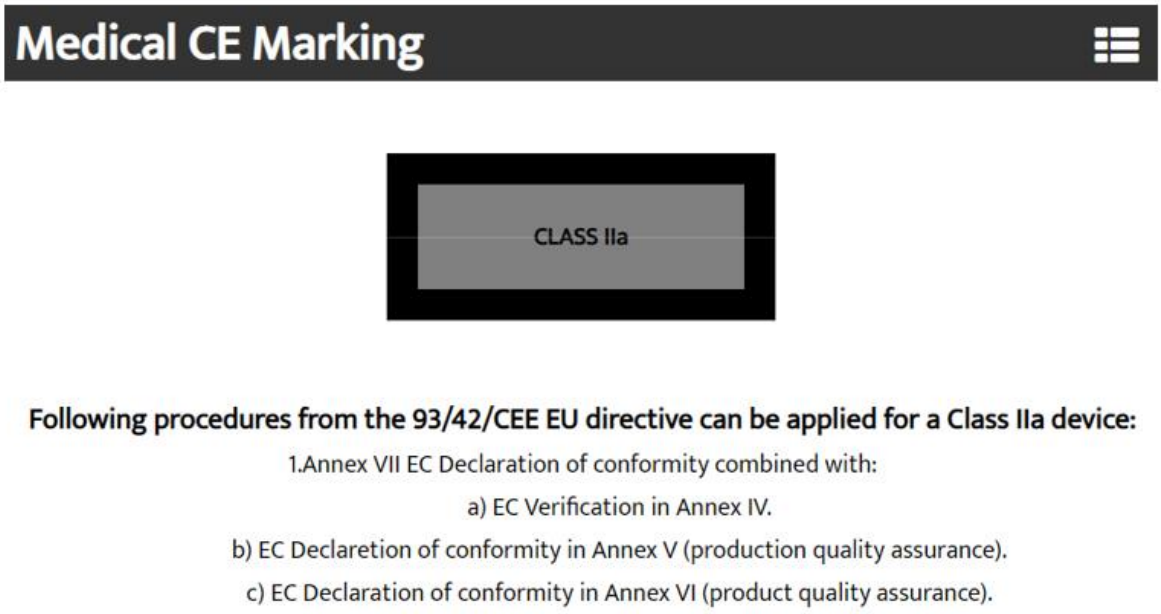

Figure 9: Example of a Class IIa device result section after the classification is completed.

Once the website has been completely designed, implementation is necessary. An online portal in the internet needs two main things to operate from external devices: a domain and a hosting. For the execution of the project, both of them have been purchased with the same company, "OVH HISPANO S.L.U.". An internet domain, as stated by the Serbian National Internet Domain Registry or RNIDS is:

> *"[…] part of a system in which Internet addresses are linked to specific locations on the Internet (servers, websites, e-mail servers etc). An* ***Internet domain*** *name is your own Internet address which you have registered as part of a national or international Internet domain. It is an integral part of a website and e-mail address and thus identifies you on the Internet"* (RNIDS, 2006).

On the other hand, the internet hosting can be defined as the service which allows individuals to share contents with the internet. There are various types of hosting, however, in the case of this project, the web hosting service has been chosen. This service allows access via the World Wide Web and provides space on a server to upload data. Figure 10 shows the OVH platform from which both hosting and domain have been purchased.

An attractive and simple domain has been chosen, which allows people searching for key words as "medical device" or "CE Marking" have a faster access to the site. Moreover, a ".com" domain has been chosen to attract international users. The following domain has been selected:

www.medical-cemarking.com

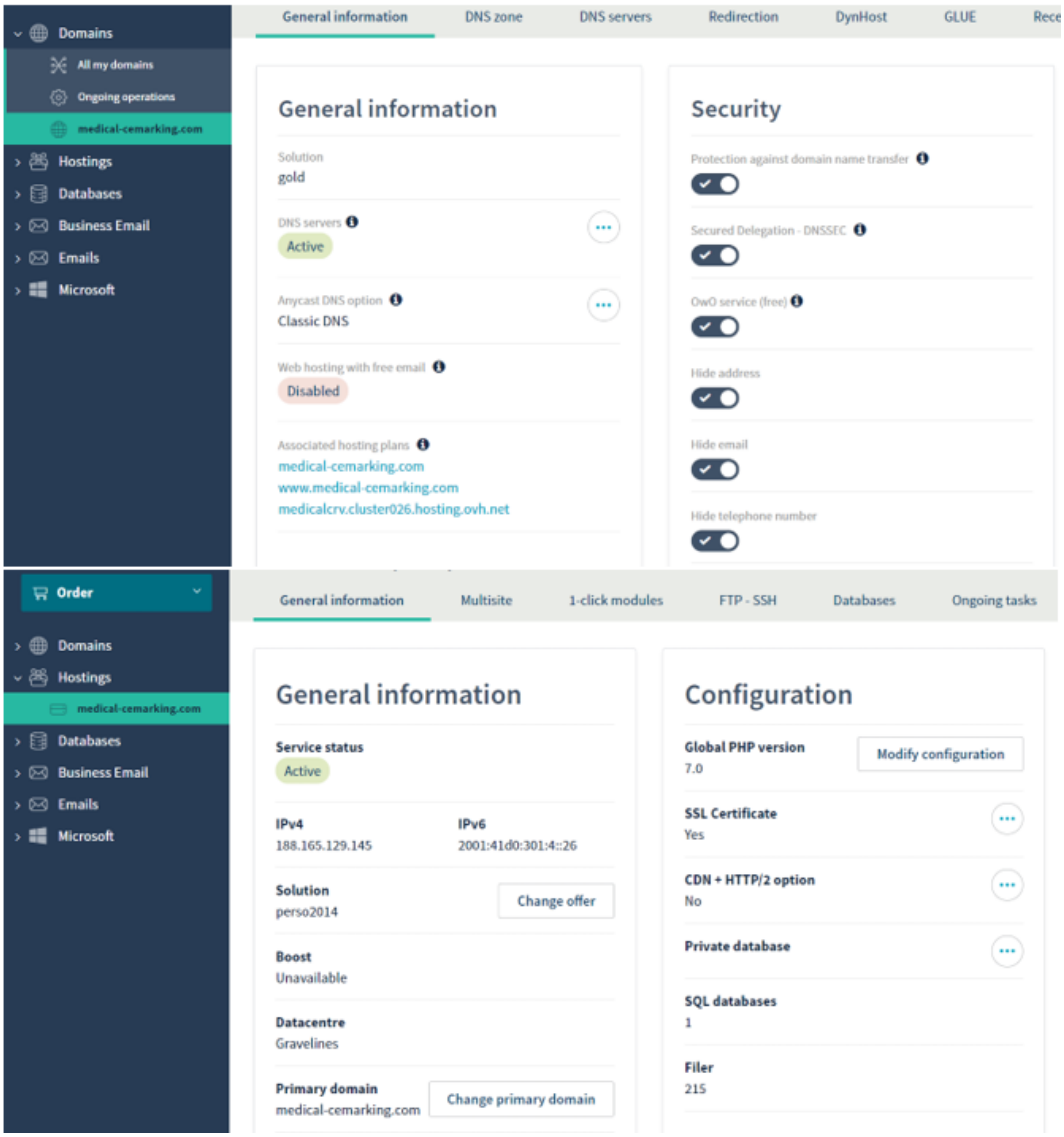

Figure 10: OVH platform from which domain (top) and hosting(bottom) have been purchased and characteristics chosen.

8.3. Phase 3: Testing and verification

Within this section a verification of both the website and classification of the products. This phase is needed to confirm that the work done meet the requirements and objectives planned at the beginning of the project. The website testing has been decided to be done by a functional testing, in which every button is tested and analysed to work as expected. Meanwhile, the classification method has been verified by a performance test. This test has consisted in conducting the online classification for different products with known results, obtained from the *"Agencia Española del Medicamento y Producto Sanitario"* also known as AEMPS, and compare them to the ones obtained in the online method.

Firstly, the functional testing has been done. The process, as mentioned above, has consisted on verifying one by one the buttons and links in the webpage. This single unit verification is also known as unit verification method. The method is similar to the one conducted while creating the website. It is common that, when using the unit testing, the developer knows how the code should behave.

Therefore, if it does not, the modification of the source code can immediately be done and re-tested until it works. As proven in the second phase, the website operates with no problem regarding the design issue.

Lastly, the performance testing has been done. This testing method might be inadequate when the number of processes is too small. Nevertheless, this method has been used due to the reliability of the results and the rapidity of the obtention of results. Within this dissertation, 2 examples have been included, in spite of being tested with a total of 25 samples. All of the samples obtained a correct classification when using the system comparing results with the AEMPS data.

The first example consists on a pacemaker. The AEMPS classifies the device as an AIMD, which in this case is a general industry pacemaker (not custom-made nor intended for investigations). Thus, the answer to the first question that Figure 8 shows is “no”. When “next” has been clicked, the second question appears, as shown in Figure 11 .

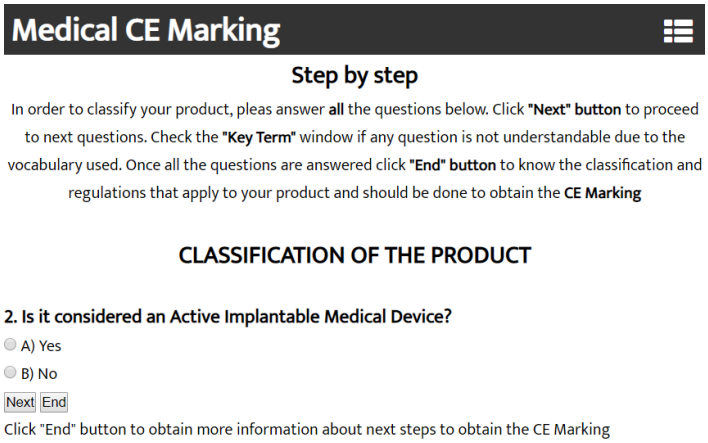

Figure 11: Second question on the pacemaker verification.

Once the device is classified as an AIMD, the next 2 questions appear simultaneously, as can be seen in Figure 12 . Once these questions have been answered, the test has been finished. Therefore, clicking “next” or “end” makes no difference for the system and the class window (Figure 13) shows directly when clicking any of them.

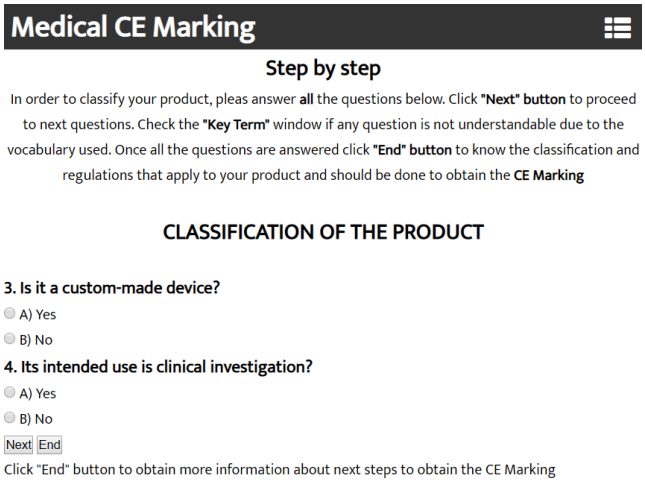

Figure 12: Third and fourth questions for pacemaker verification.

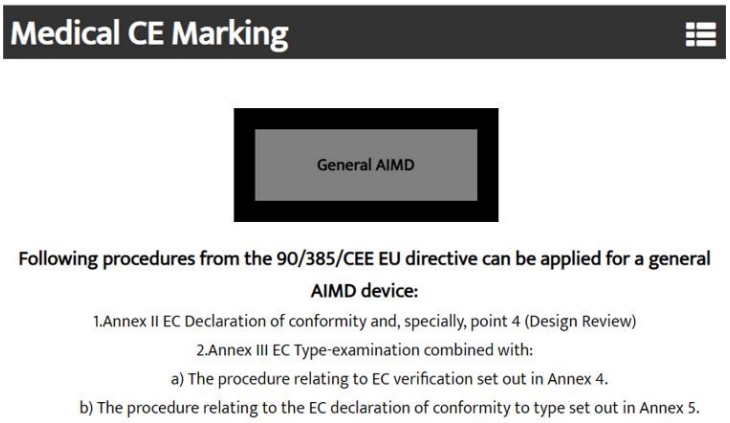

Figure 13: Results obtained for the pacemaker example

As has been proved, the result obtained from the system and the known AEMPS classification are equal and, hence, satisfactory in this case.

For the second example, absorbable sutures have been tested. As in the example above, the official classification by the AEMPS has been checked, being the device classified as Class III product. First two questions are the same as in Figure 8 and Figure 11. Once the second question has been answered and "next" button clicked, a new question will appear, as shown in Figure 14.

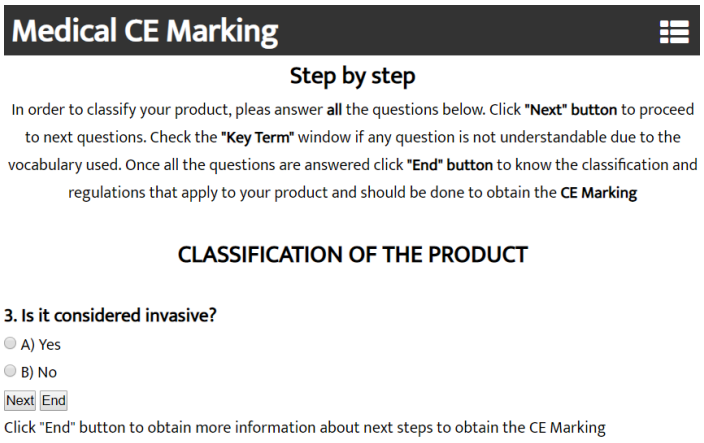

Figure 14: Question 3 for the absorbable suture example.

As this question is answered, a three-choice question appears in the system, which can be seen in Figure 15.

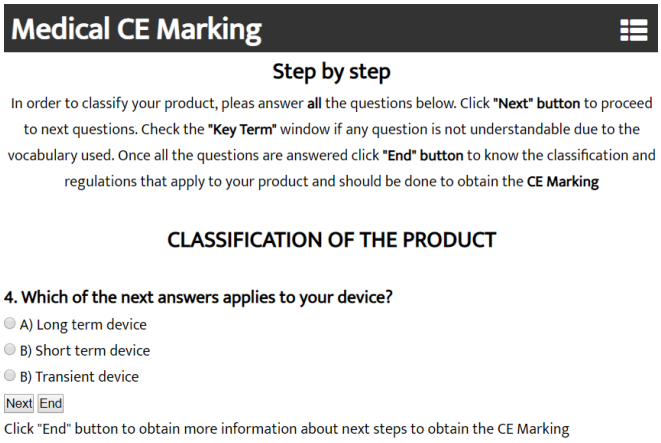

Figure 15: Fourth question for absorbable sutures.

As absorbable sutures are thought to be absorbed in less than 30 days and more than 60 minutes, the "short term device" option has been chosen. When the button is clicked, the fifth question appears in the system, as Figure 16 shows.

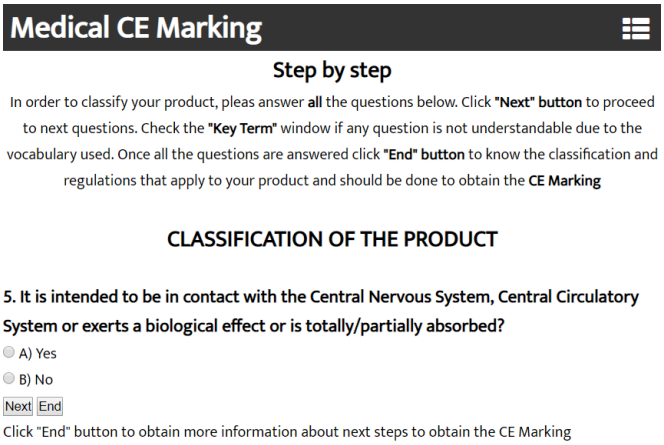

Figure 16: Fifth question for absorbable suture example.

As the sutures are absorbable, "yes" has been chosen as an answer in this question. Once this question has been answered, the product has been classified as Class III by the system, as shows. In this case, the system and the official AEMPS classification has also been the same.

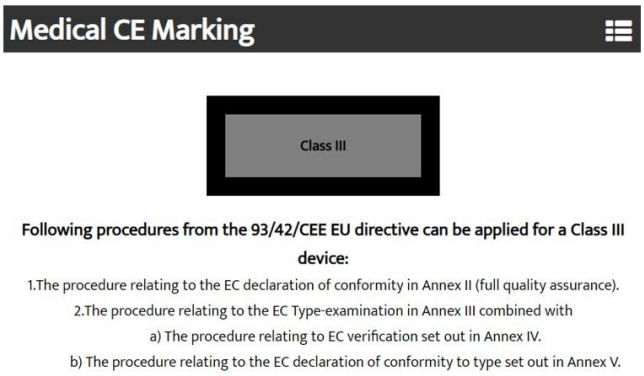

Figure 17: Results for absorbable sutures.

9. Conclusion

The aim of this project has been, in the one hand, analysing the European legislation on the medical device industry, and, on the other hand, creating an online web portal which classifies the products by the analysed legislation.

Concerning the historical study of the medical industry regulation in both Europe and Spain, it has been observed that, in the early years, economic and social issues were given more importance than safety and health issues. The creation of a single market under the name of SEA had both economic and social improvements, as Europe was still recovering from the WWII and several wars in different countries. However, the regulation was not yet strong enough to support that common market.

Regarding the legislation of the industry, it is important to mention that new regulations have been created recently. On April of 2017, the European Parliament and the Council created the "Regulation 2017/745" for medical devices and AIMD devices and the "Regulation 2017/746" for IVDD devices. These regulations are believed to apply from spring 2020 and spring 2022 respectively. As the deadline to apply the regulations seem far enough, they were not taken into consideration at the legislation analysis. Nevertheless, the use of HTML and CSS programming languages has been decided due to the easy access to the code when changes are required, as the separation in different style sheets and documents is recommended. Hence, when the new regulation applies, less time might be required to update the website to those rules.

Moreover, when verifying the performance of the classification system by means of comparing the obtained results with data from AEMPS, more tests should be done. Due to deadline, a total of 25 products were checked. All the results were positive; however, more trials should be done to guarantee a correct functioning in most of devices. This task should be conducted and added as a future guideline if the project was to be executed.

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II. TERMS AND CONDITIONS

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1. Object

This chapter includes the terms and conditions that the system, the person in charge of the system and the users have to fulfil. The objective of creating this chapter is to take a compromise between developers and users to proceed adequately while using the website.

2. Legal Conditions and References

When a user goes into the webpage, by navigating in it, the term and conditions are considered accepted. A website needs to inform the user about the requirements that they need to fulfil in order to be legally permitted to navigate into that website. Within this section, those requirements and conditions have been exposed.

2.1. System requirements

First of all, it should be noted that the system has been created for a Master Thesis dissertation and has not profitable use. Within the Spanish regulation, the *"Ley 34/2002"* or The Law of Services of the Information Society and Electronic Commerce has to be fulfilled for every electronic commerce. As the service offered by the website is free an does not ask for an economic remuneration, this law does not apply to the designed online portal.

As well as this law, there are others that have been studied in order to analyse if they were applicable or not. Those studied laws have been the following:

- "*Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal".*
- *"Real Decreto Legislativo 1/2007, de 16 de noviembre",* by which it is approved the General Law for the Defense of Consumers and Users and other laws.

In the case of the first one, it does not apply in this case due to the fact that the website does not require any information about the user at any time. Regarding the second one, as stated above, the webpage developers do not get any profit from it, due to being part of a final Master project.

2.2. Implementation conditions

The developer is responsible of implementing the system in the world wide web, having no effect on the users. As stated in previous chapters, an OVH hosting has been booked for over a year, where the programming code needs to be uploaded. The access to the uploading site is restricted to everyone but the owner of the webpage. Moreover, the website is frequently verified to make sure that the performance is the expected one.

2.3. Agreement

Within the agreement and/or legal advice of the website, it is important to make clear that, when someone accesses the online portal, it is automatically considered "user" and accepts the terms and conditions.

Moreover, the legal advice should include information about the website activity, which in this case has been decided to be as follows:

"'medical-cemarking' provides access to different information and services, from now on called content' within the internet which belong to the same owner. The user assumes the responsibility of the use of the website. The user promises to make appropriate use of the contents and services, not using them for: (i) incur in illicit activities, illegal or contrary to good faith and public order; (ii) disseminate content or propaganda of a racist, xenophobic, pornographic-illegal nature, advocating terrorism or attacking human rights; (iii) cause damage to the physical and logical systems of the owner."

It should also contain information about the intellectual property, being the website developer the only owner of the intellectual rights. However, the most important point for a web as the one developed throughout the project is the next statement about the exclusion of guarantees and responsibility:

"'medical-cemarking' is not responsible, in any case, for damages of any kind that may cause, by way of example: errors or omissions in the content, lack of availability of the portal or the transmission of viruses or malicious or harmful programs in the contents, despite having adopted all the technological measures necessary to avoid it."

Lastly, the agreement should include information about the modification of the website, links and some basic concepts. These sections would state as follow, respectively:

"the owner reserves the right to carry out without prior notice the modifications it deems appropriate in its portal, being able to change, delete or add both the contents and services provided through it and the way in which they are presented or located in the portal."

"In the event that medical-cemarking links to other Internet sites, the owner will not exercise any control over such sites and content. In no case will assume any responsibility for the contents of any link belonging to a third-party website, nor will it guarantee technical availability, quality, reliability, validity and constitutionality of any material or information contained in any of said hyperlinks or other Internet sites."

"The owner will pursue the breach of these conditions as well as any misuse of its website exercising all civil and criminal actions that may correspond by law."

III. BUDGET

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This chapter records the hypothetical costs and expenses of the project development. The objective of calculating the budget is appreciate economically the project.

1. Labour Costs

Within the labour costs, all the human hours have been calculated taking into consideration the mean salary of the professionals involved in the project. Moreover, an estimation of hours needed for the completion of the project has been calculated and proportionally stablished to each of the professional. Table 5 shown below contains the estimated budget.

Description	Amount	Unit	Price/unit	Price €
External help				
1. Programming Experts	50	Hour	13€/h	650'00€
2. Jurist (Recent graduate)	30	Hour	11€/h	330'00€
Student				
3. Biomedical Engineer	400	Hour	14€/h	5600'00€
			TOTAL	6580'00€

Table 5: Estimated labour cost budget.

2. External resources and licenses

Within this section, all the external resources needed have been estimated. These resources include office material used, every needed software, licenses and similar. The Table 6 shows the estimated data.

Description	Amount	Unit	Price/unit	Price €
Licenses				
1. Brackets	1	units	FREE	0 €
2. Microsoft Office 2016 (Student Version)	1	units	119'99$	102'62 €
Online Services				
3. Domain	1	Units	9'99€ (2'098€ IVA)	12'09 €
4. Hosting	1	Units	23.88€ (5'015€ IVA)	28,895€
Office Material				
5. Pens	1	5 Units Pack	1'15€/pack	1'15€
6. Notebook	1	Unit	2€	2€
7. USB 64GB	1	Unit	17'99€	17'99€
8. Acer Aspire E15	1	Unit	549'99€	549'99€
9. Printed Laws	100	Pages B/W	0'05€/page	5€
10. Bookbinding	100	Page to bind	0'05€/page	5€

TOTAL	724,735€

Table 6: Estimated external resources budget.

3. General budget

This section shows an overall estimation of the budget needed taking into consideration both of the previous sections within this chapter. Table 7 shows the estimated total budget.

Description	Amount	Unit	Price €
Labour Cost			**6580'00 €**
External help	60	Hours	980'00 €
Student	400	Hours	5600'00 €
External Resources			**724,735 €**
Licenses	2	Units	102'62 €
Online Service	2	Units	40'985 €
Office Material	N/A	N/A	581'13 €

TOTAL	**7304,73** €

Table 7: Estimated total expenses budget