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9253Y: Investigation of a CE Labelling Strategy for MRI Electromagnetic Field Probes

Erica Ai Li
Western University, ali385@uwo.ca

Sherjeel Anwar
Western University

Shoubhik Pandit
Western University, spandit4@uwo.ca

Sinthuja Thiruchelvam
Western University

Tristan Hilker
Western University, thilker2@uwo.ca

Exploring CE Labeling for MRI Measuring Instruments

Client Report

CE requirements, operation readiness, and expansion strategy

Allied Consulting

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Prepared by **Allied Consulting**

Erica Ai Li

Sherjeel Anwar

Shoubhik Pandit

Sinthuja Thiruchelvam

Tristan Hilker

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1. Executive Summary

As a business grows, there is pressure to expand into new markets, which led to this review. This report is connection with a company that aims to meet the MRI testing needs of its clients. The purposes of this review are (1) to assess the requirements for CE labeling certification and (2) to evaluate the European and the international markets.

Purpose 1: Requirements for CE certification
To obtain CE labeling, there is a need to follow the procedures outlined in the Measuring Instruments Directive. This includes meeting the essential requirements of reproducibility, repeatability, discrimination and sensitivity, durability, reliability, suitability, protection against corruption, information to accompany the instrument, indication of result, further processing of data, conformity evaluation, and allowable error.

After these essential requirements are satisfied, the following technical documentation must also be met:

1. A description of the measuring instrument and the manufacturing process.
2. A description of electronic devices, including drawings, diagrams, flow diagrams, software characteristics and operation (if applicable to the product).
3. A list of the harmonized standards and/or normative documents (Article 14 in the CE Directive) and the applicable references.
4. An explanation of the solutions and other relevant technical specifications done to meet the essential requirement.
5. A result summary of the design, calculations, and examinations conducted for the product.
6. An EU-type examination certification of the measuring instrument with parts identical to the proposed design of the product.

Furthermore, all of this would need to be verified by a notified body, so that a declaration of conformity can be made. After which, the CE label can be attached to the business' product and the product would be ready to enter the European Economic Area's (EEA) Market. It is important to note that there are multiple applicable CE directives to a single product. Thus, based on our analysis of how CE Labeling links to the business' product, we recommend the following course of action:

- **Revisit the 24 CE directives and identify any other possibly relevant directives for the business' product.** This allows for a preliminary overview of the work required for CE certification.

- **With the CE directives identified, review the specific steps involved for completion of each directive.** This review should follow a similar structure and sequence of steps that have been outlined in the analysis of the Measuring Instrument directive in this report. Through completing these steps, it will enhance future understanding of the time

commitment required to obtain CE labeling. This will also prepare the business' team to assemble the appropriate experts, in order to complete the essential and technical documentation.

- **Due to the complex, overlapping nature of the essential and technical documentation, it is a good idea to look over the flow charts provided in Appendices 3B, 3D, and 3E.** This allows the business to gain a consolidated understanding of the steps involved in the completion of this CE directive.

- **It is important to contact and secure a notified body early on to facilitate completion of CE certification in a timely manner.** This is because the Measuring Instruments directive requires completion of Module H, for the technical documentation, and this module requires a third-party notified body for CE assessment.

- **Allocate the same product experts to review both the essential and technical documentation.** Due to the overlapping nature of these two parts, this approach will minimize discrepancies and promote efficiency in completing the documentation.

- **Harmonized standards should be used to satisfy the relevant essential safety requirements of the measuring device directive.** Although it is not required to buy Harmonized standard directive documentations, it would be beneficial because European authorities use these documents to determine whether a product meets the essential requirements. Use of these documents can, thus, help avoid possible technical disputes over compliance because the essential requirements can often be vague and open for interpretation.

- **Since the business is the manufacturer of an MRI probe, a technical file should be created and stored for at least 10 years.** This is necessary because it demonstrates the MRI probe's compliance with the CE directives. These technical files must also be kept up to date (with all the relevant information) in the event that an enforcement agency challenges its compliance with the directives.

- **There is a need to continuously observe the updated CE labeling regulatory requirements.** This is because CE labeling requirements and the associated European directives and standards are often updated or replaced. In 2016, new CE Directives replaced the previous versions of the directive which required manufacturers, distributors, and importers to comply with the new requirements. Specific changes to the regulatory requirements will require the business to retest the probe and to update the technical documentation to assure compliance with the most recent CE guidelines.

Purpose 2: Market Analysis

Upon initial evaluations of the competitive landscape of the EEA, it is clear that there are some opportunities and threats to entering the EEA market. Some of its strongest benefits are that the industry is well developed, well funded, and growing due to an aging demographic. The European Medical Device Market accounts for 33% of the Global Market. The EEA is also home to over 27,000 medical technologies businesses. As well, it can be noted that Germany, France, and Sweden–who are part of the EEA–are world leaders in healthcare innovation. However, some of its biggest weaknesses are that there is a complex and unorganized changing legal environment that surrounds the medical device regulations. This results in a time and resource-intensive process of bringing a new product into the EEA market. Due to these weaknesses, other international markets were analyzed, and the Asian-Pacific market appeared promising. The Asian-Pacific market accounts for 60 percent of the world's populations and its medical industry is expected to grow to 133 Billion dollars in 2020 and will continue to increase by 6% every year that follows. As such, the Asian-Pacific region can be labeled as the fastest growing medical device testing market, which provides the business a promising opportunity to expand.

As a result of our analysis of European and international markets, we recommend that the business implement the following recommendations:

- **Continue monitoring the European Market and conduct a cost-benefit analysis for transitioning operations to the EEA.** Due to the unknown short-term and long-term effects of Brexit and COVID-19, and the stagnation of the EU economy, the future perspectives and stability of the European Market are unclear and must be further explored.

- **Conduct comprehensive market research on the Asian-Pacific Region, particularly the heterogenous legal environment, in order to have a holistic understanding of the competitive landscape of the region for this business.** The Asian-Pacific region is rapidly expanding its medical device manufacturing sector. Coupled with an expanding aging population and an increased demand for medical technologies, the Asian-Pacific region presents a favourable business expansion opportunity.

2. Introduction

For individuals like Joline, having an implantable medical device, such as a pacemaker, could mean the difference between life and death. Joline is 36 years old and a wife and mother. She has a heart condition that requires a pacemaker and she often gets routine check-ups for her heart. She recalls a time when she needed to get an MRI scan. The electromagnetic field from the MRI caused her pacemaker to malfunction. This incompatibility between the MRI and the pacemaker endangered Joline's life. She was hospitalized for the subsequent days while she got her pacemaker replaced. This situation created a financial strain for Joline, prevented her from fulfilling her duties at work, and took away time she had with her family. For many individuals like Joline, this situation could be avoided for the future.

2.1. Sources of Information

MRI provides useful contrast in imaging soft tissues, without imposing the risk of ionizing radiation (Nordbeck *et. al.,* 2015). In fact, MRI is considered the gold standard for detection of overall heart function. Nowadays, many patients with implanted medical devices, such as pacemakers, require that their medical devices are assessed to ensure compatibility with the MRI system. Magnetic field probes have been developed to test medical devices and the surrounding electromagnetic waves emitted by MRI systems (Attaran *et. al.*, 2019). These field probes have the ability to measure electromagnetic waves and to monitor exposure levels across different time points to ensure acceptable levels are met for patients' medical devices.

The European Economic Area (EEA) is an international agreement among 30 European countries that allows for the free movement of goods, services, and capital within the region (European Economic Area, 2020). Market expansion into the EEA provides a promising business opportunity for companies outside of Europe. In order for certain products to be sold in the European Economic Area, they have to undergo CE labelling. This label indicates that the product meets pre-established safety and environmental standards (CE Labelling, 2018). It is the sole responsibility of the manufacturer of the product to review the requirements for CE labelling and to indicate conformity to these requirements. The process of obtaining the CE marking is a lengthy process and could be financially costly for the manufacturing company. There are multiple steps to ensuring conformity, some of which include the completion of product tests by the manufacturer and by external notified bodies. For companies that are considering expansion of their product into the European market, obtaining CE certification for that product could be a formidable task.

2.2. The Opportunity

The general process of obtaining a CE mark for a product is unknown. The specific requirements for obtaining the label for a measuring instrument also needs to be determined. With these components in mind, this provides the opportunity to create a step-by-step work plan that details how to obtain CE labelling for a measuring instrument that ensures medical devices

can be safely used within MRI systems. Additionally, the opportunities and threats in the EEA market need to be further explored. This provides the opportunity to investigate the viability of the European market, as well as to explore other promising international markets.

2.3. Purpose of Report

The purpose of this report is to examine and generate recommendations for the following components:

1. **Process of obtaining CE certification.**
   We seek to assess the general steps to obtaining certification, as well as the specific steps for certification for the Measuring Instruments CE directive.
2. **Analysis of international markets.**
   We are interested in the opportunities and threats presented by the EEA market. We will also explore the feasibility of entering other international markets.

2.4. Scope of Report

This report will examine the CE labelling requirements through analysis of websites and documents available online. The work will be conducted by Allied Consulting from January 2020 to April 2020. The findings will pertain to outlining the sequence of events required for obtaining CE certification and will not focus on completing the technical product tests needed for certification.

2.5. Organization of Report

In this report, we will first explore the history of the business, followed by an examination of the current market environment and potential competitors. Then, we will explore the process of obtaining CE labelling, with an emphasis on providing practical recommendations. Next, we will analyze the feasibility of entering different international markets.

3. Background

3.1. Nature and History of the business

The company was founded to meet the MRI testing needs of other. Currently, the business has had over 100 clients, which range from large multinational medical device manufacturers to small start-ups. Up until recently, business has used this funding to focus on testing MRI devices with ISO/IEC 17025:2005 accreditation. At the core, business wants to ensure that MRI machines can be used to evaluate implanted medical devices in a manner that is compatible and safe. It is not a surprise that business' next steps are to manufacture probes that can be used to test MRI machines around the world. As a result of that and from the inquiry of a client, two key aspects to the business' future growth are to investigate CE labeling and to explore the international market around MRI testing.

3.2. Business and Market Environment

The medical device testing market is becoming more globalized as trade and business channels become more integrated. According to a market report by Grand View Research Inc. (Grand View Research, 2020), currently, the medical device testing market is worth $6.9 Billion USD and is estimated to be worth $14.6 Billion USD by 2027. This significant increase in the market size is due to advancements in pharmaceuticals and medical device development. As a result, an increase in preclinical spending has also contributed to

the growth in medical device testing.

The medical device testing market is intrinsically linked to the medical device market. The medical device market is expected to grow by 5% each year, with an estimated market size of $612.7 Billion by 2025 (Fortune Business Insights, 2019). As the medical device market continues to grow, the demand for accurate and comprehensive medical device testing will also increase. Thus, it is safe to say that the future of medical device testing will remain relevant and the demand will continue to increase.

Furthermore, the largest market for medical device testing is located in North America, with the United States having the majority of the market share in the region (Mordor Intelligence, 2019). Due to increased pharmaceutical and medical device manufacturing in the region, the North American market is expected to maintain its current trajectory. For the business, this is an ideal market environment, where it can continue to expand its operations within North America and use this momentum to develop its presence in the international medical device testing market.

The fastest-growing market outside of North America is the Asian Pacific Market. Due to the increased development of pharmaceuticals, manufacturing, and improvements in the healthcare system in the region (Agarwal *et al.*, 2016), there is an increased demand for medical device testing. Likewise, the European market is similarly experiencing an increase in demand for medical device testing. However, due to the current political and economic implications of Brexit and renegotiations of trade agreements, the current business market is quite volatile.

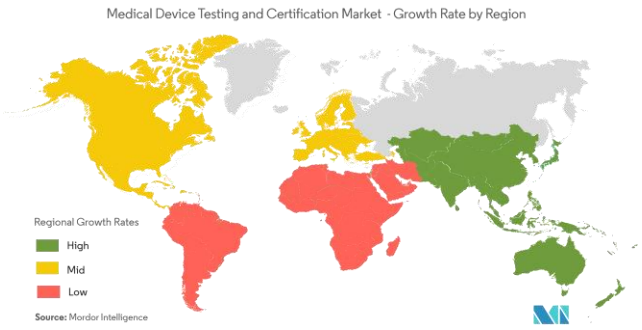

Figure A: Prospective Medical Dive Testing and Certification Market. (Grand View Research, 2020)

With the current growth of both the medical device testing and medical devices market (Figure A), the business has a unique opportunity to continue to expand its business operations within North America, capitalizing on the increasing trend of medical development, which will allow the business to increase its presence within the North American Market. As well, due to the increasing integration of the global markets, the business should begin to focus on developing its presence in high growth areas such as Europe and Asia-Pacific. By spearheading the globalization of medical device testing, the business can gain a competitive advantage, providing its services to not only large multinational medical device manufacturers but to the multitude of upcoming start-ups across the globe.

3.3. Competitors

The medical device testing market is limited to a few companies that specialize in providing medical device testing, compliance, and certifications. Most of these companies are region-specific and are specialized in providing testing and certifications that are in compliance with their respective regional authorities. However, this may provide the business an

opportunity to provide testing services to clients seeking to sell their products in other countries and regions. As the medical device testing market continues to grow and expand their influence, more companies are expected to enter the market and occupy a significant portion of the market share. Thus, it is important for current medical device testing companies to begin to expand their services to accommodate the increasing international demand.

3.4. Firm's Objectives

The business of interest aims to expand its services internationally in the near future and in order to successful transition its business operations globally, it's short-term objectives include: (1) gaining a comprehensive understanding of CE labelling in the context of medical device testing and (2) understanding the European Market and the feasibility of expanding business operations in the region. In the long-term, the business aims to have a comprehensive plan toward successfully expanding its services internationally and gaining the relevant quality certifications of the region.

4. Task Overview

4.1. Requirements for CE labeling

First, we explored the general six-step process to obtaining CE certification. This task also required a summary of CE directives that were thought to be relevant to the business. This began with summarizing the low voltage, electromagnetic compatibility, machinery, medical devices, and measuring instruments directives. Second, we conducted a thorough review of the CE certification process for the measuring instruments directive. This consisted of two parts, the general requirements, and technical documentation.

4.2. Operations readiness for CE requirements

This portion required an audit of the current business Quality Management System (QMS) and the current business technical facilities. After the audit, a gap analysis would have been conducted concerning the CE labeling requirements. This was not able to be done due to COVID-19, and social distancing, which prevented Allied Consulting's planned visit to the laboratory for the necessary audit.

4.3. International and EEA Market Evaluation

First, we conducted EEA market research and provided key findings that specifically related to the business. We noticed limitations within the EEA market. Thus, for our second component, we explored other international markets and their potential to benefit the business.

5. Exploring a CE Labelling Strategy for MRI Measuring Instruments

5.1. Current Situation

The medical device market in the European Union accounts for one third of the global market, earning over €115 billion in yearly revenue. The industry consists of over 27,000 companies all over Europe that employ nearly seven hundred thousand people. Medical technology has the highest number of patents filed with the EPO with a significant rise after 2015 (MedTech Europe, 2019).

Many European countries lead medical device innovation and export their products all over the world. The majority of these innovations are driven by small and medium sized companies (SMEs), making up around 95% of the medical technology industry (MedTech Europe, 2019). Roughly 10% of gross domestic product (GDP) of Europe is spent on healthcare and out of the total expenditure, nearly 7% is attributed to medical technology. The healthcare expenditure varies from 5% to 10% depending on the countries and the weighted average of expenditure on medical technology per capita in Europe is around €213 (MedTech Europe, 2019).

According to the MedTech Europe 2019 report, Europe is a major hub for the global medical device industry, and accounts for 27% of the world market making it the 2nd largest market after the United States of America. Europe leads the pack in terms of medical devices trade balance. Europe has a positive medical devices trade balance of €19.7 billion while US medical devices trade surplus is at €2 billion. Trade partnerships between different countries has enabled the medical devices sector to grow exponentially. In particular, Europe possesses numerous collaborations with leading medtech partners such as US, China and Japan.

Many European countries export their products to the other markets and rely on imports to supply the domestic healthcare industry. Top destinations for medical device export include North America, Asia Pacific and the Middle-East, USA, China and Japan. These regions play a crucial role as suppliers to the European medical devices market. Thus, manufacturers producing in-demand technologies will find their products may be well-received throughout the European marketplace.

Recent regulatory, economic, and political shifts in Europe could impact the medical device industry. The medical device manufacturers transitioned to the new Medical Device Regulations and ISO 13485:2016. The upcoming regulation changes to the CE mark (OBIO, 2017) will also play a crucial role as they will help decide the future of many SMEs importing their products into the European marketplace. The relatively weaker Euro may benefit European companies exporting to North America. However, it may create difficulties for importers who pay an increased tariff while complying to updated laws and regulations. Foreign manufacturers continue to compete with large, multinational corporations operating and distributing in Europe.

Products traded on the extended Single

Market in the EEA require a CE mark. The mark supports fair competition by holding all companies accountable to the same rules. A manufacturer declares that the product meets the legal requirements for CE marking and the product can be sold throughout the EEA by affixing the CE marking to the product. Products manufactured in countries other than those in the European union have to adhere to the legal requirements of the CE mark as well.

The CE mark allows businesses to know that products bearing the CE marking can be traded in the EEA without restrictions and enables consumers to enjoy the same level of health, safety, and environmental protection throughout the entire EEA. CE marking is a part of the EU's harmonization legislation, managed by Directorate-General for Internal market, Industry, Entrepreneurship and SMEs. The comprehensive guidance on the implementation of EU product rules can be found in the Blue Book.

The business' acquisition of the CE marking for their products will act as a trade license for the EEA, allowing them to freely circulate their products throughout the thirty countries of EEA. The most significant benefit for manufacturers is that the process of obtaining CE marking involves only one set of requirements and procedures to comply with in designing and manufacturing a product for the entire EEA. This eliminates the need for various and conflicting national regulations and the product no longer needs to be adapted to the specific requirements of the different member states of the EEA.

In addition, by implementing the CE requirements, the business can claim that their product will be safe for the user as it complies with the safety and health regulations of the European Union. Moreover, the marking can also reduce damage and liability claims because the CE mark indicates that compliance and quality standards of the product have been met.

5.2. Methodology

First, we assessed the general six steps for obtaining CE certification by reviewing online reports available on the official European Union website (Europe.eu, 2019) and Canada's Trade Commissioner website.

CE marking consists of 24 different directives which cover different manufactured products according to their product type. Our team narrowed down the directives which were relevant towards the business' products. These directives were namely: Low Voltage, Electromagnetic Compatibility, Machinery, Medical Device and Measuring Instruments. After thorough research and recommendations from our project sponsor, we narrowed down our focus to the Measuring Instruments directive. Thus, we then investigated the specific process of obtaining CE certification for Measuring Instruments. The essential requirements for this directive were identified along with their necessary technical requirements.

5.3. Analysis

5.3.1. Six Steps of CE labelling

Step 1: CE Directive Identification
The first step is to identify whether the product requires CE Marking as not all the products are required to be CE marked.

There are no specific steps that can be followed, as the European Commission currently does not have a comprehensive list of products that need a CE mark. CE marking is required for certain product groups or aspects of the products that fall within the scope of at least one of the 24 CE Marking Directives seen in Appendix 3F. Also, there can be more than one directive that can be applied to the product. If the product does not fall within the scope of any the CE Marking Directives, then the product does not need to be CE Marked.

A directive is a form of legislation of the European Union that sets minimum requirements for members and allows it to be placed legally on the European market. The primary objective of the CE directive is to warrant that all the products placed in the European market conform to the safety and health of the users when used in accordance with its intended purpose. As well, the guidelines are placed to ensure that products are safe for the user and maintain performance levels claimed by the manufacturer. Once the applicable directives are identified for their product, the next step for the business would be to assess product-specific requirements and conformation. (Six Steps to CE Marking, 2019)

Step 2: check for specific requirements for the product

Each directive has a slightly different methodology for demonstrating conformity. Each directive also details the legal requirements on what the European Union requires for the product to be compliant. These requirements are known as “essential requirements.” It is up to the manufacturer of the product to ensure that the product complies with the essential requirements of the relevant directives. These requirements are general in nature and do not specify specific information on how to design a product. The best way to illustrate that the essential requirements for the product can be met is by using applicable harmonized European Standards. European harmonized standards are a list of standards that are used to satisfy the relevant essential safety requirements. Harmonized standards describe details on how requirements of the directives can be met for the product. The use of harmonized standards is voluntary. For instance, a manufacturer can use non-harmonized standards or industry standards to demonstrate compliance. However, the application of harmonized standards gives a ‘presumption of conformity’ with the Essential Requirements of the Directives. Manufacturers of the product can also use other standards to ensure compliance with the essential requirements in the directives (Six Steps to CE Marking, 2019).

Step 3: identification of appropriate route for conformity

Certain CE marking directives require products to be tested and certified by a third-party organization–called a Notified Body–to ensure that the product complies with the essential requirements. A notified body is an agency approved by the European authorities to evaluate the conformity of the product with the essential requirements outlined in the applicable directives. Notified body assessment is not obligatory for all products; therefore, it is necessary to check whether it is a requirement against the applicable directives. Once the Notified body is satisfied with the compliance of the product, certification of conformity would be issued. An assessment of the product can also be

conducted by the manufacturer if the directives do not require the use of a Notified Body. This can be done by conforming to harmonized standards with applicable essential requirements mentioned in step 2. There are five directives that require manufacturers to use the notified body, and these directives include the Medical Devices directive, the Equipment and Protective Systems in Potentially Explosive Atmospheres directive, the Pressure Equipment directive, the Appliances Burning Gaseous Fuels directive, and the Simple Pressure Vessels directive (Six Steps to CE Marking, 2019).

If the manufacturer of the product conducts the conformity assessment, there are no fees for the assessment. However, if the notified body is used for independent assessment by a notified body, then the notified body must be paid for their services. There are many notified bodies that are appointed by the European Authorities, which are listed on the NANDO (New Approach Notified and Designated Organizations) database. The business can use this to find a notified body by country or by the directive. The majority of notified bodies are located in Europe, and some subsidiaries are located in Canada or in the United States to service North American clients (CE marking, 2018).

Step 4: Assessment of conformity

To prove product conformation with their essential requirements, the manufacturer needs to test and document the conformity assessment procedures. Every directive outlines conformity assessment procedures, which are referred to as modules. There are a total of 8 conformity assessment modules, which are outlined in the 2019 Six Steps to CE Marking report.

- **Module A**: Internal production control
- **Module B**: EC type-examination
- **Module C**: Conformity to type
- **Module D**: Production quality assurance
- **Module E**: Product quality assurance
- **Module F**: Product verification
- **Module G**: Unit verification
- **Module H**: Full quality assurance

Directives allow multiple different routes for products to be tested with different conformity assessment procedures. A thorough assessment of the different routes of conformity assessment will ensure that a certification route is chosen that will yield significant savings in time and money.

Step 5: Technical Documentation

All CE directives require technical documentation containing relevant information, which proves that the product conforms to their applicable directive. The technical documentation must generally include all related information about product development, any changes during the manufacturing process of the product, and information regarding the conformity of the product. The technical documentation must be maintained for at least ten years from the last manufacturing date of the product. This is essential as the technical documentation must be given to the enforcement agency to prove the conformity of the product within a short timeframe. Conformity of the product can be challenged at any time, as such, appropriate evidence must be given by the manufacturer to the enforcement agency to support the self-declaration claim. If the product is modified or is subjected to updated conformity assessment procedures, the technical documentation needs to be updated according to the

assessment procedures (Six Steps to CE Marking, 2019).

Step 6: Declaration of Conformity & Affixing of CE mark

Once the product conforms to the applicable CE directives, a declaration of conformity would need to be completed. Declaration of Conformity is a legal obligation where the manufacturer of the product acknowledges the responsibility for its compliance with the relevant CE directives. It is the manufacturer's sole responsibility to declare the conformity of the product, and it must be made available to the authorities and EU distributors at the point of entry into the European Union (Six Steps to CE Marking, 2019). An example of a Declaration of Conformity is seen in Appendix 3A.

The requirements of each directive vary and generally includes a one-page document with the following requirements:

- Manufacturer information (Name and Address)
- Product Details (Model, description of the product, etc.),
- List of CE Marking Directives and the standards used
- which standards have been used,
- Location of the conformity test results
- Information about the responsible person
- The date of the signed declaration of conformity

Once a Declaration has been finalized, the next step is to affix a CE mark onto the product. All things considered, the CE mark may not be affixed onto the product until all the conformity assessment procedures have been finalized. Affixing of the CE mark is generally done at the end of the production phase to ensure that the product complies with all the requirements of the directive. However, if the CE mark needs to be a permanent component of the product, for example, by stamping or casting, the mark can be affixed onto the product at another stage of production. This can only be done if the conformity procedures of the product have been verified throughout the production phase. The CE mark would also need to be followed by an identification number of a notified body if they have been involved in the production phase of the product. If several notified bodies are involved in the production phase of production, then several identification numbers for each notified body must follow the CE mark (Six Steps to CE Marking, 2019).

There are also imaging standards that need to be followed when CE marking a product. The initials "CE" must be clear, readable, and permanent, as seen in Appendix 3C. The CE mark should be at least 5mm unless a different dimension is mentioned in the relevant directive. If the CE mark logo is reduced or enlarged, the letters must be in proportion to the standard version. The CE logo must be placed on the product itself or its data plate. The CE mark can be affixed onto the packaging of the product if it is not possible due to the nature of the product, technical problems where the minimum dimension of the CE mark could not be met, or the CE mark was indelibly affixed due to manufacturing problems. When all these requirements have been met, the CE mark can be affixed, and the product can be legally placed onto the EU market (Internal Market, Industry., 2017).

5.3.2. Overview of the Measuring Instrument directive

The measuring instrument directive 2014/32/EU establishes all the requirements that measuring instruments have to meet in order to be made available in the European market. This directive came into effect in April 2016 and replaced directive 2004/22/EC. All measuring instruments placed on the market after April of 2016 must comply with the essential requirements and conformity procedures listed on the directive. A measuring instrument is defined as any device or system with a measurement function that is listed below. To affix CE marking to a product under this directive, the product must be proven to be durable, reliable, and suitable for the intended purpose and sensitive to accurate measurements with repeatable results (Directive, E. U., 2014). The scope of the directive applies to the following measuring instruments:

- Active electrical energy meters
- Thermal energy meters
- Measuring systems for dynamic measurement of liquid quantities (not water)
- Automatic weighing instruments
- Taximeters
- Material measures
- Dimensional measures
- Exhaust gas analyzers
- Water and gas meters
- Volume conversion devices

5.3.3. Essential Requirements

The essential requirements for CE marking comprise of 12 categories. A few of these categories are divided into subcategories to ensure complex products can attain conformity status. The first essential requirement comprises the allowable errors approved by the European Union and defines how the error of measurement should not exceed the maximum possible error value. Moreover, the manufacturer has to declare the specific environment in which the instrument is intended to be used. The reproducibility clause states that the application of the same measurement in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. Moreover, the application of the same measurement under the same conditions shall result in the close agreement of successive measurements. The requirements also state that the measurement shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task. The other categories, such as durability, reliability, and suitability are also necessary for acquisition of the CE mark. The essential requirements revolve around protecting manufacturers and consumers against corruption and prescribe different guidelines to assure counterfeiting and faulty products are not on the marketplace. Moreover, the manufacturer is required to provide specific information about their products including measuring capacity, range, and marking. Finally, an unambiguous display of measurement result should be provided with the device, which is easily comprehensible and accessible (Directive, E. U., 2014).

5.3.4. Technical Documentation

According to this directive, the technical documentation must include the design of the product, the manufacturing of the measuring instrument, and the assessment of its conformity with the essential requirements (Directive, E. U., 2014).

Measuring Instrument Technical Documentation must include the following information:

- Description of the measuring instrument
- Conceptual design, drawing, components, circuits information of the product
- Description of the manufacturing procedures
- Description of electronic devices along with drawings, diagrams, flow diagrams, software characteristics and operation (if applicable to the product)
- Descriptions and explanation for the understanding of the information in points above
- A list of the harmonized standards and/or normative documents (Article 14 in the CE Directive) and the applicable references
- Descriptions and explanation of the solutions and other relevant technical specifications done to meet the essential requirements where the harmonized standards and/or normative documents have not been applied.
- Result summary of the design calculation and an examination conducted for the product
- Applicable test results to show that the measuring instrument complies with:
    - The requirement of the measuring instrument directive under determined operating conditions and environmental disturbances
    - Durability specification for water-, gas-, thermal energy meters, and for liquids other than water
- EU-type examination certifications of the measuring instrument with parts identical to the proposed design of the product.

Conformity assessment Procedures for Measuring Instruments

Conformity assessment procedures are specified on Annex II of the directive with the ten sector-specific annexes (annex III-XI) listing procedures regarding conformity assessment for each of the ten sectors. The conformity assessment modules explaining the assessment procedures are described in annexes A to H1. The summary of each of these modules is shown in Appendix 3D. When using the measuring instrument directive, the manufacturer can choose different conformity assessments specified in the directive. It is important to determine if the product can be assessed by the company itself or whether a notified body needs to be involved. For each type of measuring instrument, there are instrument-specific assessments with different conformity procedures to choose from. Different combination of conformity procedures for measuring instruments is seen in Appendix 3E. For example, manufacturers of water meters can choose from the procedures: B+F or B+D or H1 as set in Annex II to conduct conformity assessments. Finally, an example of a pathway concerning the process of conformity type (module B) is shown in Appendix 3B (Directive, E. U., 2014).

5.4. Recommendations

Through our work, we have observed that multiple CE directives are applicable to the business' field probe. Thus, we recommend the following:

1. Revisit the 24 CE directives (Six Steps to CE Marking, 2019) and identify other appropriate directives for the business' product. This can provide an initial overview for the steps involved in obtaining CE certification.

2. For the CE directives identified in the above recommendation, we suggest reviewing the specific steps involved for completion of each directive. These specific steps will likely follow the structure we have provided in our analysis of the Measuring Instrument directive.

3. The CE marking process is extensive, costly, and time-consuming. The process is not as transparent because the requirements to obtain a CE-mark vary across different types of products. Therefore, we recommend beginning the process of acquiring the CE label early in the development phase of the product. It would also be beneficial to communicate with the appropriate notified bodies early on to ensure timely completion of third-party conformity assessments.

4. The business should use Harmonized standards to satisfy the relevant essential safety requirements of its relevant CE directive. These harmonized standard documents usually cost between 300 to 1,500 Euros. Although it is not legally required to buy these documents, it is beneficial because European authorities use these harmonized standard documents to determine whether a product meets the essential CE labeling requirements. The use of these documents can also help avoid possible technical disputes over compliance because the essential requirements can often be vague and open for interpretation.

5. Product manufacturers are required to create a technical file that needs to be stored for at least 10 years. The technical documentation should outline the product compliance with the CE directives. It is recommended that all technical files with all relevant information be kept up to date in the event of an enforcement agency challenging its compliance with the directives.

6. It is recommended that the business constantly monitors changes to the CE mark regulatory requirements. Older versions of CE Directives requirements were updated in 2016, requiring manufacturers, distributors, and importers to comply with the new requirements. These changes require the manufacturer to retest the product and to update the technical documentation that proves compliance with CE requirements. Therefore, continuous monitoring of regulatory requirements is recommended.

Through completing these steps, this will enhance future understanding of the time commitment required for CE certification. This will also prepare the business' team in assembling the appropriate experts to complete the essential and technical documentation.

Additionally, after reviewing the step-by-step process of fulfilling the Measuring Instruments directive, we recommend the follow next steps:

1. Due to the complex, overlapping nature of the essential and technical documentation, we suggest reviewing the flow charts provided in Appendices 3B, 3D, and 3E to consolidate understanding of the steps involved in completion of this CE directive.

2. As the Measuring Instruments directive requires the successful completion of Module H for the technical documentation, a third-party notified body will be required to assess compliance for CE certification. To ensure a timely completion of CE certification, it is best to connect with a notified body early in this process.

3. It may be beneficial to allocate the same product experts to review both the essential and technical documentations. Due to the overlapping nature of essential and technical documentations, this approach will minimize discrepancies and promote efficiency in completing the necessary documentation.

6. Exploring European and International Markets

6.1. Current Situation

In order to better understand the feasibility of the CE labeling strategy, it is pertinent for the business to have a detailed understanding of the European economic landscape and alternative regional markets.

As previously mentioned, the European medical device market is the second-largest market, accounting for a third of the world's global market (MedTech Europe, 2019). It consists of over 27,000 companies ranging from micro firms to multinational corporations. As one of the healthcare leaders in the world, Europe plays a significant role in healthcare innovation and manufacturing and as the development of medical devices increases, the need for accurate and comprehensive medical device testing will similarly increase. This presents the business with a favorable opportunity to expand its presence within the region. A market analysis will be conducted to evaluate the competitive landscape of the EEA and the viability of expanding the business' services in this region.

6.2. Methodology

In order to gain a comprehensive and detailed understanding of the international economic environment, market research and market analysis was conducted to understand the EEA and other global markets. Open-source online market reports were also used for our analysis.

6.3. Market Analysis of the EEA

According to Appendix 2, the EEA presents a breadth of opportunities for the business. From the favourable manufacturing environment, growing medical devices sector, and increased demands for medical services for the elderly, there is the opportunity to service the needs of this region. However, due to the complicated legal environment, and the unknown short and long-term impacts of Brexit and COVID-19, the barriers to entry into the EEA are increased and the potential success of the business in the EEA is unclear.

6.4. Asian-Pacific Economic Region

The Asian-Pacific region is one of the fastest-growing markets in the world and it accounts for over 60% of the world's population (Agarwal *et al*., 2016). The medical device industry in the region is expected to grow to $133 Billion USD in 2020, on par with the European market and is expected to have a growth rate of 6% (Grewal *et al.*, 2016). As well, the region has a rapidly growing medical device manufacturing sector and a growing medical device testing market.

Furthermore, the region is experiencing a rapidly aging population, with China, South Korea and Japan having a large and growing elderly population (Lau, n.d.). In particular, over a quarter of Japan's population consists of the elderly and with a declining birth rate, the country is expecting to see the elderly population significantly increase. There will likely be a growing need for medical device testing in order to meet the healthcare needs of this aging population. Additionally, within the region, there is a growing middle class, which increases buying power and enables individuals to access more medical devices

and tests.

The various governments in the region recognize the increased healthcare burden placed by the elderly population and thus have been increasing health expenditures and investing in improving and maintaining existing healthcare infrastructure and medical technologies. Due to the increased demand for medical services and devices, this provides organizations like the business the opportunity to expand its presence in this region and to take advantage of the growing need by governments in this region.

Additionally, within the Asia-Pacific region, there is a lack of a unified quality standard or governing body to regulate overall medical device imports and product quality (Lee, 2019). Rather, each individual country or economic bloc has distinct medical device regulations and product quality standards (Lee, 2019). As a result, some products and services may comply for one country but not comply for another. Due to the heterogeneous legislative environment, the business may experience barriers to entry in certain countries due to varying compliance requirements.

6.5. Recommendations

The EEA presents many favorable opportunities for the business to expand its presence, however, due to the threat of COVID-19 and the impact of Brexit, the viability of expanding operations into Europe is still not clear. Therefore, we recommend to continue monitoring the European Market and to conduct a cost-benefit analysis to understand the potential gains and losses the business may incur if they transition their services to the EEA.

On the other hand, the Asia-Pacific region—due to its rapid growth and increasing demand for medical devices—is an attractive alternative to the European Market. Therefore, we recommend that the business conducts a comprehensive market research on the Asia-Pacific region and evaluate the competitive landscape in the region in the future.

7. Summary Conclusions

Purpose 1: Requirements for CE certification

In this report, we have shown that there are six general steps to obtaining CE certification. These steps include the following:

1. Identifying relevant CE directives
2. Pinpointing the essential requirements for each CE directive
3. Determining whether a third-party assessment is required
4. Assessing product conformity
5. Fulfilling necessary technical requirements
6. Declaring product conformity

For our work, we have outlined the steps involved for certification of the Measuring Instrument directive. However, it is important to note that multiple CE directives likely apply to a single product. The following may also apply to the business' product: Medical Devices directive, Machinery directive, Electromagnetic Compatibility directive, and Low Voltage directive. Therefore, we recommend the following course of action: First, we suggest revisiting the 24 CE directives (Six Steps to CE Marking, 2019) and identifying if there are any other relevant directives for the business' product. This can provide a preliminary overview of the amount of work required for CE certification. Second, for the CE directives identified, we recommend reviewing the specific steps involved for completion of each directive. This review will likely follow the structure and sequence of steps we have outlined in our analysis of the Measuring Instrument directive. Through completing these two steps, this will enhance future understanding of the time commitment required for CE certification. This will also prepare the business team in assembling the appropriate experts to complete the essential and technical documentation.

Through our analysis of the Measuring Instruments CE directive, we have noted that there are two parts that must be fulfilled: essential documentation and technical documentation. The essential documentation involves 12 steps, which ensure the reliability of the product's performance. Each step involves documenting test outcomes that indicate the product meets the requirements for each step. The technical documentation involves four parts, each of which contains tests that must be performed, and design figures that must be provided, in order to demonstrate the product's proper functioning. After reviewing, the step-by-step process of fulfilling the Measuring Instrument directive, we recommend the following next steps: First, due to the complex, overlapping nature of the essential and technical documentation, we suggest reviewing the flow charts provided in Appendices 3B, 3D, and 3E to enhance understanding of the process involved in completion of this CE directive. Second, because the Measuring Instruments directive will require completion of Module H for the technical documentation, a third-party notified body will be required for CE certification. Thus, we recommend contacting and securing a notified body early on to facilitate completion of CE certification in a timely manner. Third, we recommend allocating the same product experts to completing both the essential and technical documentation. Due to the overlapping nature of these two parts, this

approach will minimize discrepancies and promote efficiency in completing the documentation.

Purpose 2: Market Analysis

After analyzing the EEA market, we have identified pertinent opportunities and threats to starting business in this region. In terms of opportunities, the European Medical Device market accounts for 33% of the Global market (MedTech Europe, 2019). This provides a large existing workforce which the business can tap into to manufacture and sell their product. However, a potential threat is the complex and unorganized legal environment, involving both CE labelling and EU directives. On top of the administrative complexity of fulfilling numerous guidelines for a single product, these guidelines are also updated regularly. Thus, obtaining CE certification will be a time-intensive process, requiring internal and third-party experts to ensure the product meets evolving CE guidelines. Overall, after conducting this preliminary EEA market analysis, we recommend the following: First, a more comprehensive cost-benefit analysis can be conducted to further explore the feasibility of entry into the European market. Second, due to the time- and labor-intensive process of obtaining CE certification, we recommend exploring other international markets which possess a lower barrier to entry. For the remainder of this report, we have explored the feasibility of entering the Asian-Pacific market. However, other markets may also be explored in the future.

The opportunity in the Asian-Pacific market lies in its large population, accounting for 60% of the world's population (Agarwal *et al.*, 2016). This region is experiencing a dramatic increase in its elderly population and subsequently, a growing need for medical device testing. Asian governments are increasing their spending to improve healthcare infrastructure (Agarwal *et al*., 2016), which provides the opportunity for the business to take advantage of this Asian-Pacific market. Furthermore, there is an absence of a unified governing body to regulate medical device quality within this region. This can provide a lower barrier to entry compared to the EEA market. Thus, after conducting this initial analysis of the Asian-Pacific market, we recommend performing a more thorough analysis of the competitive landscape in this region. The medical industry in this region is expected to grow 6% every year (Agarwal *et al.*, 2016), which could present as an opportunity—in terms of growing consumer need—or as a challenge—in terms of increased competition from related medical device firms.

Overall, CE certification is a multi-step process that, once obtained, may allow the introduction of the business' product into a large Medical Device market. Due to the complexities of obtaining CE certification, the feasibility of expanding into other international markets may also be explored. It is our hope that through this work, we may minimize incidences of medical device incompatibility. We hope that in the future, many more individuals across the globe—like Joline—can regain control over their health.

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8. Appendices

Appendix 1: Comparison of Healthcare Expenditures

	EUROPE	UNITED STATES	CHINA
Population	515,052,778	321,368,864	1,367,485,388
Primary language(s)	German, English	English	Chinese, Mandarin
Total healthcare spending	$1.80 trillion	$3 trillion	$574 billion
Healthcare expenditures total (% of GDP)	10.0%	17.1%	5.5%
Healthcare expenditures per capita	$3613 (USD)	$9403 (USD)	$420 (USD)
Expenditures on healthcare	Government: 78% Private: 22%	Government: 48% Private: 52%	Government: 56% Private: 44%
Size of medical device market (USD)	$14.5 billion (USD)	$147.7 billion (USD)	$8.7 billion (USD)
Number of hospital beds	5.4 per 1000 people	2.9 per 1000 people	3.8 per 1000 people
Age distribution	0-14 years: 16% 15-64 years: 65% 65 years and over: 19% (2016 est.)	0-14 years: 19% 15-64 years: 66% 65 years and over: 15% (2015 est.)	0-14 years: 17% 15-64 years: 73% 65 years and over: 10% (2015 est.)
Life expectancy at birth	Male: 77 years Female: 83 years	Male: 77 years Female: 82 years	Male: 73 years Female: 78 years
Currency	Euro (€)	US dollar ($)	Renminbi yuan (¥)

Appendix 2: Market Analysis of the EEA

Strengths:
- European Countries spend over 10% of GDP on Healthcare, 7.5% consisting of medical devices and technologies
- Well-Developed Medical Industry and Strong Manufacturing Base
- Large Qualified Workforce; Over half a million workers within the region
- Growing Medical Device Industry

Weaknesses:
- Complex and Unorganized legal environment
- Extensive CE labeling requirements and compliance to various EU regulations and directives
- Complicated Administrative Process
- Time and Resource intensive
- Lack of Coordination Between Academia and Industry

Opportunities:
- Aging Demographics; 23% of the population over the age of 60
- Expanding Middle Class; increased spending power and demand for medical devices
- Increasing demand for international exports to North America and Asia

Threats:
- Brexit; short-term and long-term effects are unknown
- Changes in Medical Device Regulation; Medical Devices CE directives predicted to change May 2020
- Stagnation of European Economy: growth at 0.1% for 2020

Appendix 3: CE Labelling Requirements and Directives

European Declaration of Conformity

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorized representative established in Community (1)

.....
.....

declares that the new PPE described hereafter (2)

.....
.....

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard No ..... (for the PPE referred to in article 8 (3)

is identical to the PPE which is the subject of EC certificate of conformity No.....
issued by (3)(4)

.....
.....

is subject to the procedure set out in article 11 point A or point B (4) of Directive 89/686/EEC under the supervision of the notified body(3)

.....
.....

Done at ....., on .....

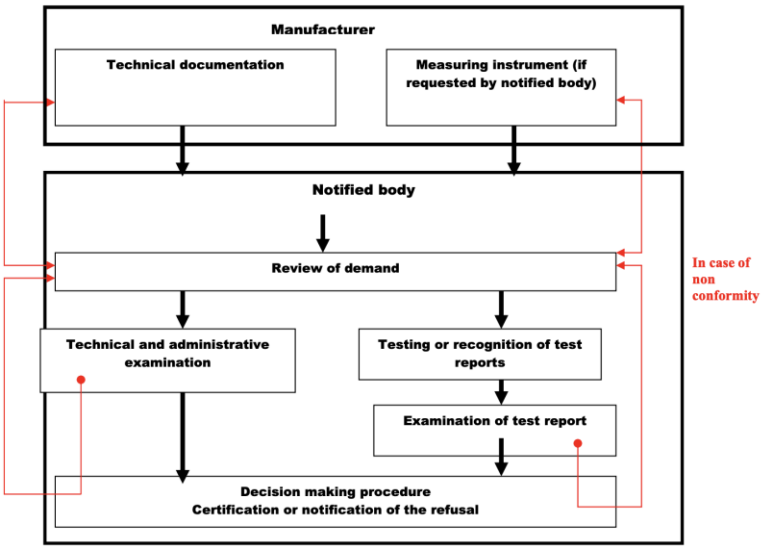
.....
Signature (5)

(1) Business name and full address; authorized representatives must also give the business name and address of the manufacturer.
(2) Description of the personal protective equipment (make, type, serial number, etc.).
(3) Name and address of the approved body.
(4) Delete whichever is inapplicable.
(5) Name and position of the person empowered to sign on behalf of the manufacturer or his authorized representative.

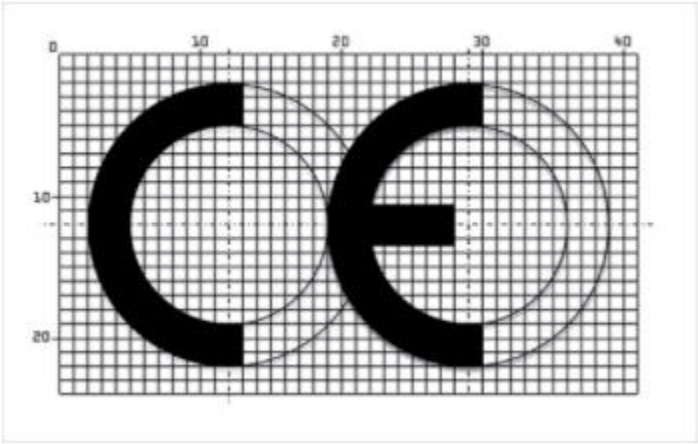
Appendix 3A: Example of Declaration of Conformity (Six Steps to CE Marking , 2019)

Annexe 1 : Example of process of an EC type examination

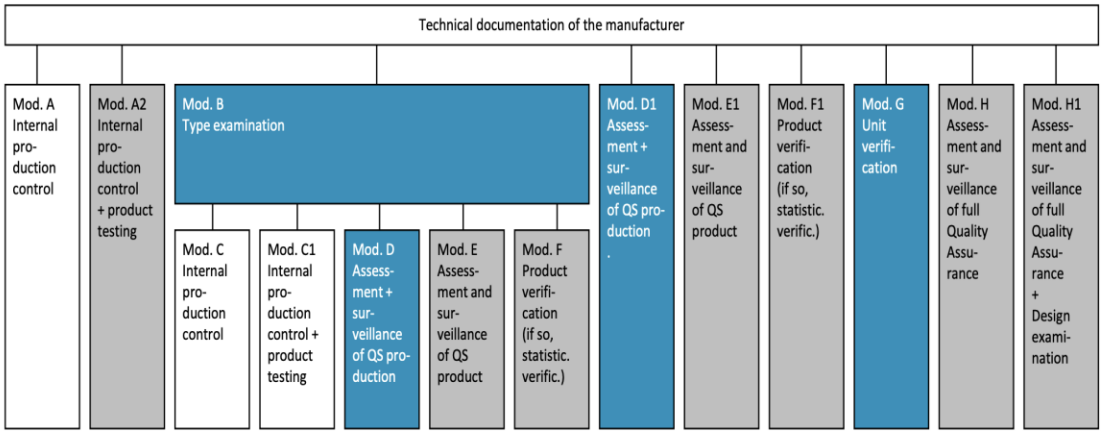
General statements concerning process of conformity evaluation of a type (module B) are usually the following:



Appendix 3B: Example of conformity assessment procedure for different modules (Measuring Instruments Directive 2004/22/EC, 2007)



Appendix 3C: CE mark Image Requirements Example (Internal Market, Industry, Entrepreneurship, 2017)



Appendix 3D: Technical Documentation of the Manufacturer (Criteria and procedures for the approval, 2016)

Directive	Product group	Possible conformity modules
MID	Water Meters - MI-001	B+D, B+F, H1
	Gas Meters and volume conversion devices - MI-002	B+D, B+F, H1
	Active electrical energy Meters - MI-003	B+D, B+F, H1
	Heat Meters - MI-004	B+D, B+F, H1
	Measuring systems for continous and dynamic measurement of quantities of liquids other than water - MI-005	B+D, B+F, G, H1
	Automatic weighing instruments - MI-006	Mechanical systems: B+D, B+E, B+F, D1, G, H1 Electromechanical systems: B+D, B+E, B+F, G, H1 Electronic systems or systems containing software: B+D, B+F, G, H1
	Taximeters - MI-007	B+D, B+F, H1
	Material measures - MI-008	Material measures of length: B+D, B+F, G, H1 Capacity serving measures: A1, B+D, B+E, D1, E1, F1, H
	Dimensional measuring instruments - MI-009	Mechanical or electromechanical: B+D, B+E, B+F, D1, E1, F1, G, H, H1 Electronic instruments or instruments containing software: B+D, B+F, G, H1
	Exhaust gas analysers - MI-010	B+D, B+F, H1

Appendix 3E: Conformity Modules (“Conformity modules relevant to ATEX,” n.d.)

Directive Number	Product Category
2006/95/EC	Low Voltage
2009/105/EC, (ex. 87/404/EEC)	Simple Pressure Vessels
2009/125/EC	Ecodesign for Energy-related Products
2000/14/EC	Noise Emission for Outdoor Equipment
2009/48/EC 88/378/EEC, 93/68/EEC	Toy Safety
89/106/EEC, 93/68/EEC	Construction Products
2004/108/EC	Electromagnetic Compatibility
2006/42/EC	Machinery
89/686/EEC, 93/68/EEC, 93/95/EEC, 96/58/EC	Personal Protective Equipment
2009/23/EC (ex. 90/384/EEC)	Non-automatic Weighing Instruments
2009/142/EC (ex 90/396/EEC)	Appliances Burning Gaseous Fuels
92/42/EEC, 93/68/EEC, 2004/8/EC, 2005/32/EC	Hot-water Boilers (liquid or gaseous fuels)
93/15/EEC	Explosives for Civil Uses
93/42/EEC, 98/79/EC, 2000/70/EC, 2001/104/EC,	Medical Devices
2007/47/EC	
90/385/EEC, 93/42/EEC, 93/68/EEC, 2007/47/EC	Active Implantable Medical Devices
98/79/EC	In Vitro Diagnostic Medical Devices
94/9/EC	Equipment Explosive Atmospheres
94/25/EC, 2003/44/EC	Recreational Craft
95/16/EC	Lifts
97/23/EC	Pressure Equipment
99/5/EC	Radio Equipment and Telecommunications Terminal Equipment
2000/9/EC	Cableway Installations to Carry Persons
2004/22/EC	Measuring Instruments
2007/23/EC	Pyrotechnic Articles

Appendix 3F: **24 CE Directives** (Six Steps to CE Marking, 2019)