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Quality Control in Telemedicine - “CE” Label

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1. Introduction

As explained previously [1], the European Directive for Medical Devices (MDs) and equipment, the DIR 2007/47/EC [2], aims at achieving the goal of quality of medical delivery at a distance, providing comparable demands in telemedicine or distance support as in face-to-face healthcare.
The transposition into Spanish law of the EU directive was the Royal Decree RD-1591/2009, dated 16 October 2009 [3], which regulates the use of medical devices called “PRODUCTOS SANITARIOS (PS)” (= health-care products) in Spanish, which came into force on the 21st of March 2010. As from that date, the **CE-Label** is always required in all “MDDS or Medical Device Data Systems” according to the FDA.
In this article, we will explain the philosophy behind the EU-Directive and the Spanish RD with respect to quality in medical assistance. We will also try to demonstrate that the same norms apply to Telemedicine, and we will finally underline the importance of training medical and health-care workers in those aspects linked to the Body of Knowledge of Telemedicine as well as in the essential safety aspects linked to medical assistance. These professionals may indeed be guilty of infringing the law and liable if the law is not applied. As is well known, ignorance of the law is no excuse. This has indirect consequences on the training and licensing of health-workers. •

2. Medical device- definitions

According to the EU directive and the transposed RD:
The definition of an MD in the RD (in Spanish) is based on the European Commission Directive 2007/47/ec which defines a medical device as <<any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used 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.

This includes devices that do 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.>>
An MD is not a medicine in the sense that it does not produce its principal effect inside or on the surface of the body by pharmacological, immunological, or metabolically active substances, but whose function may contribute to them.
The so-called "in vitro" diagnostic systems are not covered by the 1591/2009 decree; they are regulated by the RD-1662/2000 decree.
The goal of the EU directive as well as that of the RD is to guarantee a quality system for MDs with periodic inspection and control by means of 5 distinct procedures:

1. **EXAMINATION of the CE type** is defined as the procedure by which a **NOTIFIED BODY tests** a representative sample of the product and **certifies** that it is in accordance with the RD demands**.** The result is the CERTIFICATION of the MD-type.
2. **CE-VERIFICATION** is defined as the procedure by which the **MANUFACTURER** or its authorized representative **guarantees and declares** that the products are in **conformity** with the **MD-Type described** in the certification of the CE-examination, and that **they fulfill all the requirements** set out in the RD. The conformity declaration includes a statement according to which the manufacturer agrees to guarantee the product after its sale and installation and to correct any defect that could occur.

This means that the manufacturer must implement all required controls and tests linked to the MD-type.

3. & 4. **CE DECLARATION OF CONFORMITY** for the **PRODUCTION** and the **PRODUCT** is defined as the procedure by which the MANUFACTURER puts into practice all warranty requirements **and declares** that all the products are **in conformity with the MD-type** described in the Certificate of the CE-examination, and that they fulfill all the requirements set up in the RD.

This means that the manufacturer must implement the whole quality system to assure conformity not only of the final product but of the whole production.

Part of this task is to guarantee the organizational structures and the responsibility of the directives, the methods of efficacy in the function, and the control to third parties, whenever applicable.
Furthermore, a **VALIDATION REPORT** should accompany those MDs whose **function is "measurements".**

This is the case of Telemetry and distance measurement that require a VALIDATION REPORT before being authorized for use in real world situations. This is an important qualitative difference from the previous situation in which software systems had to be validated by the users and hospital before being used. Now, the software as an MD requires a previous Validation Report by the manufacturer.

Similarly, the manufacturer whose products require "**connection with other products"** to work must provide proof that their products fulfill the essential requirements once

connected to other products according to the manufacturer's goal or to those specified as **a special purpose** (custom made[1], research[2], etc.).

This means that for any product connected to another to send information, the manufacturer must guarantee that this information is not altered in any way (manipulation, lost information, lossy compression, encryption, etc…), and must not be integrated without a Validation Report.
In other words, the manufacturer is responsible for the integration processes, whether added functions are included or not.

5. **CE-LABEL.** Only those products with a CE-Label will be authorized to appear on the **market and to be used in medical practice**. The CE-label will always be accompanied by the identification of the Notified Organ responsible for the evaluation procedures.
   Exceptions for the CE-Label are:
   a. As an exception, products or devices built for one person or for clinical research do not require CE-Label.
   b. For medical devices and products for which the Certificate of Conformity **does not require the intervention of the NOTIFIED BODY (these are the Type I devices),** the CE-Label will not carry an identification number assigned by the Notified Body.

*This means that the CE-label is mandatory for all MDs or Health Products, but that those included in the **Type I group** will not carry an identification number.*

   c. According to the RD, CE-Label conformity is not required for those MDs that are not included in article 2, paragraph 1, points a) and b)-

Therefore, the CE-Label only applies to MDs together with their ACCESSORIES.

To ensure the product guarantee, the manufacturer must be able to demonstrate CE-Label conformity during a period of 5 years, but for implantable MDs or products, the period is 15 years. This information must be available to the authorities in charge of quality control.

Therefore, in order to claim for any malfunctioning or defect of the product, we should understand the terms defined in the law, particularly the term MANUFACTURER.

Custom-made devices are intended for the sole use by a particular patient and produced in accordance with specifications prescribed by a qualified practitioner. A mass-produced MD that only needs adaptation is not a custom made device. Custom- made devices do not carry a visible CE mark, but remain subject to the Medical Device Directive (MDD) requirements.

[1] 'Custom made' means that the device is for one patient only and should carry his/her name as well as the name of the medical doctor who authorized it (encrypted or not) along with the medical prescription.
[2] Guarantee for patients in the trial, permission from the ethical committee as well as the medical doctor and center authorization must be provided.

The manufacturer must issue a statement of conformity for each device stating the patient's name, device identification, and responsible medical practitioners.

2.1 Definitions

In the RD the following terms of importance are defined:

Manufacturer: the person or legal entity responsible for the design, manufacture, packaging and labeling of the MD to be **introduced on the market** in his own name, regardless of whether any of these operations are carried out by the same person/entity or by a third party.

Introduction on the market: this term refers to the first time an MD or Health product, **not designed for clinical research**, arrives on the market with or **without economic transaction** (i.e., for free), for its **distribution and/or use** in the EU market, regardless of whether it is a new or a totally refurbished product.

This means that a manufacturer is a person or legal entity who produces an MD whether it is for financial profit or not, whether it is produced voluntarily or by contract or even by mandate within an organization in a public or a private system, provided that the medical device is used in the real world (i.e., not only for research) in a country member state of the EU.

Commercialization: any **provision**, with or without economic transaction (i.e., **for free)**, for its **distribution or use** in the EU market during a commercial activity.

This means the real use of the product coming from a manufacturer to a final user for its real use, regardless of whether the transaction involves financial gain or not.

Deployment: refers to the phase in which a product, **prepared to be marketed in the EU** for the first time **according to the manufacturer's intended goal**, **is given to the final user.**

Goal assignation: The use for which the MD is built according to the indications of the manufacturer in the labeling of the product, user's instructions and/or marketing material or flyers.

This means that, although the manufacturer does the product either by contact, for free o by obligation, the device should have, before any use, a label with user's instructions and a detailed specification explaining why the system was built and validated for according to the manufacturer.

Medical specialist: a medical doctor or any other person with accredited professional qualifications who is **legally authorized** to issue a medical prescription or **to perform biomedical research**.

This means that the validation of a system must be performed, tested and supervised by a specialized medical doctor.
Obviously, a medical specialist must supervise medical assistance from the very start, whether this assistance is provided for research or for regular assistance.

Promoter: manufacturer, legal representative or any other **person or organization** that becomes **responsible for the indications** and/or deployment of a **clinical research.**

This means that a promoter is a person who indicates an MD "deployment" by giving it to the final user for free or after payment. This activity is usually performed by the local health-care authorities with MDs and products of the software and telemetry types, specifically designed at a regional or "in house" level for local healthcare use.

Chapter II of the RD specifies that the manufacturers should be registered and should possess a previous license to operate in order to make sure that they have an **organizational structure capable of guaranteeing the quality of their products** and the performance **of the procedures and controls** mentioned above. They have to have a **technical responsible** personnel, with an **university-licensure (title)** that assure an **ad-hoc qualification** to control and supervise the product in charge; furthermore, his availability for this task must be demonstrated devoting a sufficient **labor time-schedule**. Finally he should carry out a series of documents to collect all information produced during product-manufacture. These documents should include the **design, production and capabilities** of the product so as to check the conformity of the product to the essential requirements (*i.e in a software application to encrypt clinical information in order to send it at distance, documents should demonstrate that the application fulfill the data-protection law. This could avoid for example the case to steal and disseminate sensitive information located in the memory chip of the printers once those are replaced or even when those are repaired…*)

If this is the case, local health-authorities that produce their own software for medical-clinical-assistance should be registered and required to fulfill the same demands as any other manufacturer. And of course, once in public call for tender, it should be mandatory to include those requisites for enterprises applying the call to build "regional" or "in house" assistant systems.

However, the RD also mentions that the Spanish Agency of Medications and Health Products could **authorize, in an individualized and specific manner** and based on health care considerations, the marketing and deployment of products that **have not satisfied all the validation procedures** indicated in article 13.

We hope that, for the final users' safety, there will be few such exceptions to the norm, and that this provision for exceptions will never become a repetitive practice. An example of the use of this exceptional authorization put into practice in the case of medication was the vaccination campaign against influenza A (H1N1): the vaccine did not fulfill all the requirements to be on the market.

3. Essential information & definitions relevant for health care workers

The RD starts a procedure to understand the design, manufacture and applications of the product together with the design, risk analysis, investigation and clinical trials etc., with respect to product safety, including **electromagnetic compatibility** and radiation protection, as well as ergonomic **design** and the **level of training** of future users[3].

[3] Training should also involve the medical doctors as users.

That means that the manufacturer must train users to assure that they will use the device in a proper manner, without risk for patients and health care workers, and to make sure that they know their liability when using it. Therefore, the liability for the products and devices introduced on the market is the manufacturers.
This also clearly applies to local healthcare authorities if they act as manufacturers.

As specified above, based on the level of potential risk to the human body, MDs are classified as one of four types: types I, IIa, IIb y III.
The higher the number, the greater the risk. In the lowest risk class (type I MD), the evaluation is the exclusive responsibility of the manufacturer. For the other types, the evaluation is performed by a "NOTIFIED BODY" appointed by national authorities to issue a **Certificate of Conformity.**

As we will see, most Telemedicine systems are classified as type I MDs because they are not invasive. Thus, they do not require a number or a Certificate of Conformity from the "Notified Body". Nevertheless, it is mandatory for them to carry the CE-label. This means that, under the responsibility of the manufacturer, the device must meet the requirements for quality and safety demanded for any MD and be supported by documents proving that verification and manufacture control etc., have been carried out. These documents must be available to the competent authorities in case of any legal demand or claim.
A problem arises when the so-called "competent authority" coincides with the manufacturer or is the entity that establishes the system requirements in the call for tenders.

This is why all MDs require initial classification by the manufacturer as one of four types for the CE-label, as follows:
Type I- NON INVASIVE PRODUCTS[4], with the exception of those connected to higher type numbers or in contact with human body substances, fluids or tissues. These comprise all PSANI-**P**roducto **S**anitario **A**ctivo **N**o **I**nvasivo (in English: non-invasive Active Medical Device) with the exception of the cases that we will study further on.
INVASIVE PRODUCTS FOR A SHORT PERIOD OF TIME (less than 60 min) and those used in the natural orifices (oral cavity up to the pharynx, external ear conduct up to the tympanic membrane, nasal cavity).
Type II-ALL INVASIVE PRODUCTS, including the PSA-**P**roductos **S**anitarios **A**ctivos (In English: Active Medical Devices). These exclude invasive surgical devices connected to a type I MD. This group is divided into two sub-groups, as follows:
IIa- MDs USED for A LIMITED PERIOD OF TIME (up to 30 days). This includes those used in wounds or around micro-wounds and surgical invasive devices, except those used for monitoring, diagnosis, surveillance, and cardio-circulatory correction. Those invasive to natural orifices that are connected to a PSA type IIa (active device type IIa). Dental implants. All products for diagnosis or surveillance of non-critical vital signs[5] and those involved with the introduction of non-harmful substances in the body. Products used for disinfection.
IIb- MDs USED FOR LONG PERIODS OF TIME (more than 30 days). Those MDs or products carrying ionizing radiation, having a biologic effect, capable of being absorbed by

[4] All active software and telemedicine devices belong to this group.
[5] Among these are all telemetry systems (including vital sign telemetry if the patient is not in a critical condition. It therefore refers to the classical home-care), tele-ultrasonography, etc.

the human body or capable of being modified by it. Any active MD connected to a type IIb[6] or PSAI -**P**roducto **S**anitario **A**ctivo **I**nvasivo (In English: Invasive Active Medical Device). This includes all MDs for the surveillance of critical vital signs[7] and those that are potentially harmful[8] because they introduce substances into the body. Blood bags. Contraceptives. Contact lenses, disinfection products.
Type IIb also include all implantable products, with the exception of dental implants, cardio-vascular or central nervous system implants, and those that produce chemical or biological changes in the human body.
Type III- Surgical instruments which are in contact with the Central Nervous System and cardio-vascular system, or MDs that are absorbed or produce a biological or chemical modification in the human body. Products containing human blood or derived products (hemo-derivatives). Contraceptive devices used for long periods of time. All products that contain animal tissue or their derivatives.
The RD specifies that any substantial changes in an MD or Health product must be notified to the "Notified Body". The RD specifies that all MDs, health care products and their ACCESSORIES must carry the CE-label, numbered by the Notified Organism, except for Type I MDs which must exhibit the CE-label, but which are not numbered.

Type I-MDs, despite carrying a non-numbered CE-Label (which means that the product is not certified by a "Notified Body"), must be supported by documents demonstrating that the product has been subjected to the same quality control process. These documents will be required any time by the authorities when claims or civil and penal liability arise.

The Royal Decree, which is complex to understand, aims at implementing international standards on quality control in the production, design and vital cycle of the product, such as the UNE EN 60601-1:2008, IEC 60601-1/2005, ISO 14971:2007, IEC 62304:2006, etc.

This means that those devices showing the CE-label must provide a guarantee of information (there will be no secret products); of security (required to be tested in clinical trials); of functionality (they require a previous validation before marketing and real functioning); of quality design (they should have a quality design ISO-13485). If not, the device or product can only be considered as ***a demonstrator[6].***

3.1 Definitions

In the previous paragraphs, we defined what is considered a MEDICAL DEVICE or a HEALTH CARE PRODUCT. Here we introduce definitions relevant for health-care workers, such as:
An MD or PRODUCT FOR CLINICAL INVESTIGATION: **this** is an MD or product devoted **to a medical specialist**[9] **to carry out the research** in an adequate clinical human environment.

[6] i.e: more than 30 days Home-care.
[7] Vital sign telemetry including EEG y EEC.
[8] Harmful for the organ or due to the type of substance.
[9] This means that a telemetry system or a telemedicine device cannot be in the hands of an engineer (Take into consideration that innovation units, tele-ictus units and so on… are leader by engineers) nor the i+D+D projects that involve clinical research or clinical trials.

A RE-USABLE SURGICAL INSTRUMENT is one that is not connected to an active MD or PSA.

An **ACTIVE-MD** or PSA (*implantable-PSAI or non- implantable-PSANI*) is any MD that requires electrical power or any other energy source different from the one coming from the human body, or that is due to gravity, and that transforms this energy (i.e., *telemetry systems*). All **SOFWARE PROGRAMES** are considered **Active-MDs**. Excluded from this group are those MDs used for transmitting provided that there is no significant modification, energy, substances or other elements from an active-MD to the patient.

The criteria of Software programs are those that allow diagnosis, treatment, follow up, prevention, whether or not they include artificial intelligence. The latter could be as a completely autonomous or when those results are taken by healthcare workers to make decisions with respect to a local or distant patient (at home; tele-ictus; anti-cloth treatment; telemedicine in general). And although administrative computer programs (HIS-Hospital information system) will probably be excluded from future regulation, the EMR or Electronic Medical Record is directly linked to them. The EMR contains essential elements for patients' treatment or follow up that involve liability of medical doctors, such as medical orders, or electronic prescription requiring a legally recognized digital signature, and that in any case requires strict QUALITY CONTROL and therefore should be included in the RD. Many EMR and applications for e-prescriptions contain decision rules on treatment protocols, assistance to the diagnosis, prescription, patient surveillance or follow up that transform them into an Active-MD that requires active quality control [7].

The problem arises when those computer programs without quality control are developed and updated by the health-care authorities either at the national or regional or local level as "in house" "custom" products for health-care. In private healthcare entities, quality control could be easy to provide since the company responsible for marketing and supplying those products for real use is in effect the manufacturer and is subject to control by the local authorities. However, in local public authorities the manufacturer and the controller may be the same entity. This is so even if the manufacturer is an outside company contracted through a call for tenders, since the requirements for the design are established by the local authority and in many cases this is limited to compatibility with other in-house applications and not to manufacturing quality control. Being aware that manufacturing quality control items are titles and preparation of the developers, legal-preparation, time devoted for the technical personnel in the design, who is responsible for the life cycle of the product, who is responsible for the necessary technical migration in 3-5 years time to update technology and security (i.e. electronic signature, cipher according to law, to adapt to registration and certification organisms, management of new parameters and medical devices, etc….). And more specifically in wireless active-MD (telemetry) or not (WIFI hospitals) the degree of interaction of their magnetic fields with other monitoring or measurement systems are not verified or tested properly because the assembly is done "in house" without verification of the quality control.

This is regardless of the requirements of **CONFORMITY** which are defined as an MD following national norms taken to **implement harmonized standards to fulfill essential requirements** and officially published in the Government bulletins.

Thus, software manufacturers will be responsible during the whole active-life of the product. Being Type I or low risk MDs, the products will not require auditing by law, except if there is a claim, but as medical software, they will be regulated by the IEC 62304:2006 standard.

The European Commission stresses the need to use standards in order to ensure connectivity that should include semantic and technical norms, and physics of connectors and cables. However, national standards that determine the connectivity of telemetry and telemedicine systems are still to be established.
With respect to telemedicine, the minimum connectivity specified by the WHO is the IEEE 11073 [8]. Following the guide for validation of automatic systems (GAMP- Good Automated Manufacturing Practice)[9], bioengineering hospital services should control the operative systems, the hardware and the software embedded in the systems, as well as COTS (Commercial-off-the-shelf) software, configurable systems and any modification of PIMS (Personal Information Manager Software).
Furthermore the CMM or Capability Maturity Model for software[10] in their version 1.3 established VALIDATION and VERIFICATION at level 3, requiring thereafter level 4 or the quantization of processes and level 5 of Optimization. And it should be kept in mind that in many software health-care applications, even level 3 is missing[11].

4. USA ahead

As predicted elsewhere [12], the Obama health reform has forced the adoption of medicine at a distance (telemedicine) in order to optimize resources and reduce costs in the system.
The USA are very concerned about quality control and have created several government organizations to guarantee the quality control of medical assistance, standardization and connectivity, establishing minimum requirements to obtain a quality label. One of the most interesting bills passed by the US Congress is the ARRA (the American Recovery and Reinvestment Act of 2009) aimed at stimulating the use of IT (Information Technology), but what is surprising is the provision for penalties after 2015 for those professionals and organizations that do not use connective solutions. [13].
We will therefore see the time when those responsible for education and health-care will accept that all these technologies have to be integrated into the professional training. This implies that telemedicine and bioengineering applied to telemedicine will become core subject matters in the university degree of Medicine [14].

5. Summary

The transposition of the EU Directive DIR 2007/47/EC into European countries will improve the quality of the Telemedicine software and devices [15][16]. Nevertheless, health-care authorities have not yet understood the important requirements and the level of changes they will have to introduce. This is in part due to the fact that this information is not taken into consideration in the training of health care professionals.
The discipline of Telemedicine and e-health is mature if we take into consideration the level of standards existing nowadays. In contrast, maturity of the IT applications in health care is far from being optimal. This is in part because we associate maturity with penetration and not with quality, and mechanisms to ensure a quality control of the applications are still to be built.

Abbreviations

AIQ Analytical Instrument Qualification | **CFR** Code of Federal Regulations | **CSV** Computer System Validation | **EMEA** European Medicine Evaluation Agency | **EU**

European Union | **FDA** U.S. Food and Drug Administration | **GAMP** Good Automated Manufacturing Practice | **GLP** Good Laboratory Practice | **GMP** Good Manufacturing Practice | **ISMS** Information Security Management System | **ISO** International Organization for Standardization | **USP** United States Pharmacopeia

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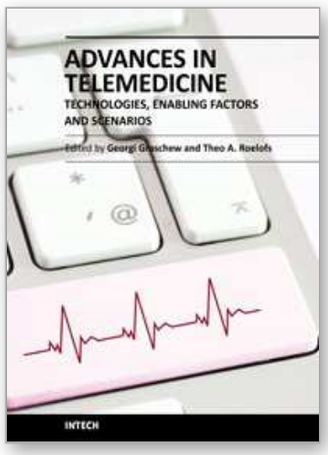
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Advances in Telemedicine: Technologies, Enabling Factors and Scenarios

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Innovative developments in information and communication technologies (ICT) irrevocably change our lives and enable new possibilities for society. Telemedicine, which can be defined as novel ICT-enabled medical services that help to overcome classical barriers in space and time, definitely profits from this trend. Through Telemedicine patients can access medical expertise that may not be available at the patient's site. Telemedicine services can range from simply sending a fax message to a colleague to the use of broadband networks with multimodal video- and data streaming for second opinioning as well as medical telepresence. Telemedicine is more and more evolving into a multidisciplinary approach. This book project "Advances in Telemedicine" has been conceived to reflect this broad view and therefore has been split into two volumes, each covering specific themes: Volume 1: Technologies, Enabling Factors and Scenarios; Volume 2: Applications in Various Medical Disciplines and Geographical Regions. The current Volume 1 is structured into the following thematic sections: Fundamental Technologies; Applied Technologies; Enabling Factors; Scenarios.

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