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REVIEW PAPER

# Preparing the certification of software as a medical device: a european regulatory analysis and case study on the Clynx®Platform

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## Abstract

**Purpose:** The primary objective of this study is the preparation of the certification of the Clynx® Platform, a physiotherapy software, as a Class IIa medical device software in accordance with the regulatory framework outlined in Medical Device Regulation 2017/745 (MDR).

**Methods:** The methodology involves a comprehensive analysis of European Union medical device regulations and guidelines, with a specific focus on the certification process essential for obtaining a Conformité Européenne (CE) marking for Class IIa medical device software. This section explores the intricate aspects of the certification process, emphasizing the compilation of Technical Documentation, the nuances of Clinical Evaluation, and the establishment of a Quality Management System. The approach aligns closely with the stipulations of MDR 2017/745.

**Results:** The study includes an industry case study featuring the Clynx® Platform, developed by Clynx® Health. Insights derived from the MDR are applied to categorize an in-development version of the software as a Class IIa medical device. The preparation of certification of this product involves the meticulous creation of Intended Use, Classification, General and Safety Performance Requirements, and Clinical Evaluation files, the presentation of an experimental protocol to validate the software's technical performance for inclusion in the Clinical Evaluation, and a description of an Internal Audit performed on the Quality Management System.

**Conclusion:** The certification of Class IIa medical device software necessitates the compilation of thorough Technical Documentation, including an extensive Clinical Evaluation, and the implementation of a robust Quality Management System. The certification process is conducted in collaboration with Notified Bodies, ensuring adherence to the stringent requirements set forth by the regulatory framework.

**Keywords** Medical device · Medical device regulation · Certification · CE marking · Technical documentation · Clinical evaluation

## 1 Introduction

Medical devices have a rich history, evolving alongside human progress and becoming increasingly specialized and complex due to scientific advancements [1, 19].

Regulation in this industry was prompted by concerns over patient safety [3], leading to the establishment of the Medical Devices Directive 93/42/EEC (MDD)[1] by the European Union in 1993. However, the MDD had shortcomings, including issues with post-market safety monitoring and transparency.

In April 2017, the EU introduced the Medical Devices Regulation 2017/745 (MDR)[2], aiming to transform the medical device landscape by introducing a robust regulatory framework to enhance clinical safety and public health. The MDR imposes more rigorous pre-market controls, particularly for high-risk devices, establishes the European Medical Devices Database (EUDAMED)[3] for real-time monitoring,

Extended author information available on the last page of the article

[1] To be consulted at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042

[2] To be consulted at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN

[3] To be consulted at: https://ec.europa.eu/tools/eudamed/#/screen/home

implements a Unique Device Identifier (UDI) system for traceability, and ensures compensation for patients receiving defective products.

This article is structured as follows: Section 1 introduces the topic of medical device certification and outlines key regulations. In Section 2, the fundamental concepts and procedures outlined in the MDR 2017/745 are presented, specifically focusing on certifying software as a class IIa medical device. Section 3 translates these principles into practical application through a real-life case study featuring the Clynx® Platform, providing a hands-on demonstration of the certification process. Finally, Section 4 highlights the contributions of this research to the regulatory landscape of medical devices.

## 2 Medical device regulation

The European Union oversees medical device regulations, and each member state designates a competent authority to enforce these regulations named Notified Bodies (NBs). NBs are essential entities for certifying medical devices, responsible for conducting conformity assessments and issuing CE markings. The EU maintains an updated list of Notified Bodies in the member states[4].

The MDR is a comprehensive document that can be challenging for manufacturers to interpret. To simplify and optimize its implementation, the EU, as the Medical Device Coordination Group (MDCG)[5], and EU-approved entities, such as the International Standardization Organisation (ISO)[6], produce support documentation. The MDCGs are guidance documents to assist stakeholders in applying the MDR; while not legally binding, they are expected to be followed. The ISOs cover core aspects, but must be complemented with the fulfilment of the MDR's specific requirements.

Next, we will outline the key steps in medical device certification and provide a guide on how to fulfil them in accordance with the MDR 2017/745 and relevant support documentation.

### 2.1 Qualification as a medical device

The first step on medical device certification is assuring that the product falls under the definition of a medical device, according to MDR 2017/745.

According to the MDR (we refer the reader to Article 2 for the complete definition), a **medical device** refers to any instrument, apparatus, software, or other item created by the manufacturer for various medical purposes, including diagnosis, prevention, monitoring, treatment, or alleviation of diseases, injuries, disabilities, or anatomical/physiological processes. It includes devices used for in vitro examination of specimens from the human body and devices for conception control and cleaning/sterilization of other medical devices. These devices do not primarily act through pharmacological, immunological, or metabolic means within the human body, but may be aided by such means [5, 11]. It is important to note that any solution designed with a clinical purpose is considered a medical device and must adhere to the regulatory requirements outlined in the MDR to be eligible for commercialization in the EU.

The MDR also provides crucial definitions related to the characteristics of medical devices, particularly concerning their power resources. In accordance with Article 2 of the MDR, an **active device** is defined as any medical device that depends on an external power source, excluding sources derived from the human body or gravity. Software falls under the scope of active devices [5].

What sets **Medical Device Software** (MDSW) apart from software is its intended use, aligning with the MDR's medical device definition. To ensure clarity, the MDR specifies that software qualifies as a medical device when the manufacturer designs it for specific medical purposes, as outlined in the defined criteria. Yet, generic or lifestyle/well-being software, even in healthcare contexts, do not fall under the medical device category.

### 2.2 Classification

The next step in medical device certification involves classification according to the MDR 2017/745, with devices falling into one of four classes: Class I, Class IIa, Class IIb, and Class III, based on patient risk. Classification rules are detailed in Annex VIII of MDR 2017/745 [5], with **Rule 11** being relevant for MDSW.

**Rule 11** states that software meant for diagnostic or therapeutic decisions is Class IIa, except if it could lead to severe harm or death (Class III), or significant harm or surgery (Class IIb). Software for monitoring physiological processes is Class IIa, unless it monitors vital parameters with immediate danger potential (Class IIb). All other software is Class I.

For MDSW, classification hinges on the significance of information it provides and the patient's clinical condition[11, 13], as depicted in Fig. 1.

[4] To be consulted at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

[5] To be consulted at: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

[6] To be consulted at: https://www.iso.org/home.html

| State of Healthcare situation or patient condition | Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy | | |
|---|---|---|---|
| | **High** Treat or diagnose *~ IMDRF 5.1.1* | **Medium** Drives clinical management *~ IMDRF 5.1.2* | **Low** Informs clinical management *(everything else)* |
| **Critical** situation or patient condition *~ IMDRF 5.2.1* | **Class III** *Category IV.i* | **Class IIb** *Category III.i* | **Class IIa** *Category II.i* |
| **Serious** situation or patient condition *~ IMDRF 5.2.2* | **Class IIb** *Category III.ii* | **Class IIa** *Category II.ii* | **Class IIa** *Category I.ii* |
| **Non-serious** situation or patient condition *(everything else)* | **Class IIa** *Category II.iii* | **Class IIa** *Category I.iii* | **Class IIa** *Category I.i* |

**Fig. 1** Classification guidance on Rule 11 of MDR, specific for MDSW. Image extracted from [11]

## 2.3 Technical documentation

Technical Documentation (TD) comprises a collection of documents that provide comprehensive and unambiguous information about the medical device. It includes device description, design, performance, safety data, risk assessment, product validation, and vigilance plans. The guidelines for TD production are detailed in Annexes I, II, and III of MDR 2017/745. Annex I outlines the General Safety and Performance Requirements (GSPR), Annex II specifies TD contents, and Annex III explains Post-Market Surveillance (PMS) procedures [5]. Some key components of a medical device's TD include:

- *Intended Use* This section defines the medical device's intended purpose and its users, addressing their medical needs and qualifications [5].
- *Classification* This document details the classification procedure according to Annex VIII of the MDR, outlining which rules are applicable to the device based on its characteristics and operation mode [5].
- *General Safety and Performance Requirements (GSPR)* As outlined in Annex I of the MDR, it sets general rules for compliance, focusing on design, manufacturing, and information provision [5].
- *Risk Management System* It assesses and manages risks associated with medical devices, aiding in hazard identification, risk estimation, and implementation of control measures [5]. ISO 14971[16] offers manufacturers a framework for efficient risk analysis and control in medical device production.
- *Device Identifiers* The document should list all device identifier numbers. The Unique Device Identifier (UDI) is an alphanumeric code following global standards, enabling clear device identification and traceability. It includes a UDI Device Identifier (UDI-DI) unique to each manufacturer-device and a UDI Production Identifier (UDI-PI) for unit identification. The Basic UDI-DI is the primary identifier for a device model, essential for database records and certificates [5].
- *Clinical Evaluation (CEv)* CEv is the systematic process of continuously collecting, analysing, and assessing clinical evidence to verify a medical device's safety and performance. It occurs before and after market deployment. According to the MDCG Guideline 2020-1, clinical evidence could be: **Scientific Validity**, which establishes, backed by scientific data, the use of the medical device, drawing on research, proof of concept studies, clinical investigations, and performance studies; **Technical Performance**, where it is demonstrated the accuracy, reliability, and precision of the device's output based on input, aligning with user needs and intended use; and lastly, **Clinical Performance**, which confirms the device's ability to provide clinically relevant output as intended [5, 12]. The process commences with a Clinical Evaluation Plan (CEvP), outlining the clinical development strategy from preliminary investigations to pivotal trials. Subsequently, a Clinical Evaluation Report (CEvR) details the results of the evaluation, providing essential evidence for regulatory compliance.
- *Post-Market Surveillance (PMS)* PMS, described in Annex III of the MDR, includes a vigilance plan to

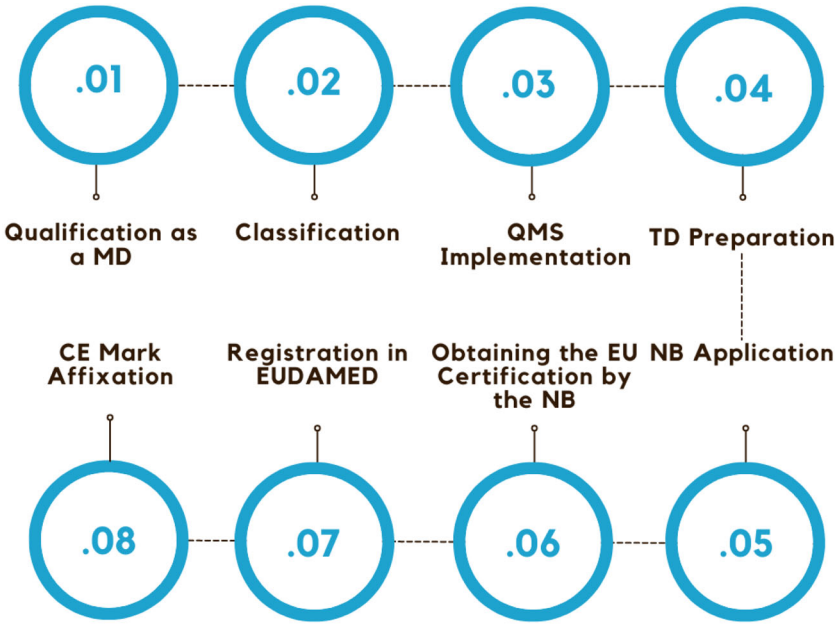



**Fig. 2** Summary of main steps to obtain the CE marking as a medical software

ensure the device's quality and performance after market entry, involving user information collection, benefit-risk analysis, and corrective actions. The *MDCG 2022-21 - Guidance on Periodic Safety Update Report according to MDR 2017/745*[7] assists with implementing the Periodic Safety Update Report (PSUR) requirements under the MDR, which is mandatory for class IIa MDs [5, 14]. The Post-Market Clinical Follow-up (PMCF) is an ongoing process integral to the PMS. It involves actively collecting and evaluating clinical data from CE-marked devices used within their intended purpose [5].

## 2.4 Quality management system

The Quality Management System (QMS) is a vital requirement for certification for medical devices, depending on their risk class and type. It provides a comprehensive framework that covers all aspects of a manufacturer's organization related to quality, including processes, procedures, and the devices themselves. It governs structure, responsibilities, procedures, processes, and management resources necessary for ensuring compliance with MDR 2017/745, covering areas such as risk management, post-market surveillance, product improvement, and incident reporting [5].

*EN ISO 13485 - Quality Management System Requirements for Medical Device Manufacturers*[8] is a crucial framework. Although certification is not mandatory, organizations can gain valuable benefits from adopting its standards. Audits conducted by NBs confirm adherence to EN ISO 13485, underscoring its significance in achieving regulatory compliance and upholding quality standards in the medical device industry. EN ISO 13485 is specifically tailored for organizations involved in medical devices and related services, with a focus on risk management and regulatory obligations. It covers requirements related to documentation, management responsibilities, resource management, product development, and processes for measurement, analysis, and improvement [8].

## 2.5 Certification process

For medical devices to enter the EU market, obtaining the *Conformité Européenne* (CE) marking is mandatory. This marking attests compliance with regulations such as the MDR and is achieved through a rigorous conformity assessment process, which falls into one of three types:

- *QMS and TD assessment* Manufacturers must establish and maintain a robust QMS and create clear, organized, and comprehensive TD for their devices. PMS documentation, including a PMS plan and PSUR, is also required.
- *Type examination* This verifies that a device, its TD, and production processes align with the MDR.
- *Product conformity verification* Manufacturers can choose between *Production Quality Assurance* and *Product Verification* methods to ensure devices conform to EU type-examination certificates and the MDR.

[7] To be consulted at: https://health.ec.europa.eu/system/files/2023-01/mdcg_2022-21_en.pdf

[8] To be consulted at: https://www.iso.org/obp/ui/en/#iso:std:iso:13485:ed-3:v1:en


**Fig. 3** Real-time feedback by posture alerts during the game. Image obtained from Clynx® Health

Once all required documentation, including TD and QMS, is prepared, it needs to be submitted to and validated by NBs, for Class IIa and higher devices.

With the CE marking acquired, the medical device can be marketed in the European market. It must also be registered in EUDAMED, which is currently under development but expected to be fully functional by 2025.

For a summarized overview of the steps required to obtain the CE marking for Class IIa medical device software, refer to Fig. 2.

## 3 Case study: the Clynx Platform certification

The Clynx® Platform[9], developed by Clynx® Health, represents an innovative gamification tool designed to enhance the rehabilitation experience for physiotherapy patients. Specifically crafted for musculoskeletal and neurological therapy, including applications in prevention, pre- and post-surgery, and chronic diseases, the platform is poised to revolutionize physiotherapy practices.

Comprising a patient-oriented Desktop Application and a specialized Clinical Portal for healthcare practitioners, the Clynx® Platform incorporates cutting-edge technology to guide patients through their exercises. The Desktop Application employs a 3D camera to provide real-time data, facilitating an engaging and interactive rehabilitation process. Simultaneously, it meticulously records session details, such as duration and repetitions, contributing to comprehensive patient progress tracking. The Clinical Portal serves as a dedicated platform for physiotherapists, allowing them to assess the adherence to treatment plans by patients. This centralized hub facilitates efficient management of patient profiles and session assessments, streamlining the healthcare professional's workflow.

[9] To be consulted at: https://www.clynx.io/

The current version of the Clynx® Platform qualifies as a medical device software, meeting the criteria for classification as a Class I medical device under Rule 11. This classification is attributed to the platform's primary function, which is to perform therapy, distinguishing it from tools primarily designed for diagnostic or therapeutic decision-making. Notably, the platform does not monitor physiological processes or quantitatively measure anatomical or physiological parameters, aligning with Sub-Rule 11 c) [4, 5].

Clynx® is working on an upcoming version of the platform. This evolution aims to aid healthcare professionals by enabling the tracking of patient progress through kinetic parameters. The new Clinical Portal will further support management of patient data, treatment plans, and assessments. The new iteration of the Clynx® Platform will not only retain its core features, including motion capture through a 3D camera and gamified rehabilitation exercises, but will also introduce additional functionalities to meet the evolving needs of both patients and healthcare practitioners, such as:

- *Real-time feedback* It will detect posture errors during exercises and provides immediate warnings to patients, offering therapeutic guidance (cf. Fig. 3).
- *Quantitative measurements* The software will gather data on exercise errors, range of motion, performance distance, and reaction time. These measurements aid healthcare professionals in therapeutic decision-making.
- *Clinical and motion data collection* The software will compile quantitative measurements and presents graphical representations of a patient's progress, facilitating the adaptation of treatment plans based on patient evolution (cf. Fig. 4).

### 3.1 Related work

Several companies are actively participating in the digital physiotherapy market, offering various solutions for neuro-

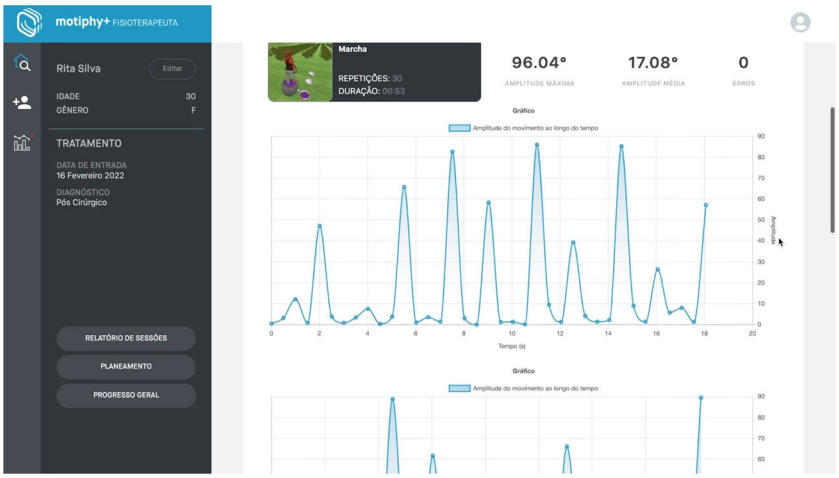



**Fig. 4** Quantitative measurements report after session. Image obtained from Clynx® Health from a simulated patient data

musculoskeletal interventions. Within the existing landscape, Sword Health's® solution boasts a class II medical device certification from the Food and Drug Administration, United States of America (FDA), while getUBetter® is recognized as a class I medical device software, certified by the NHS. Curovate® and Physiotec® have attained certification as medical devices, though their specific classification is not provided (although they are likely to be classified as Class I). On the other hand, there is a dearth of publicly accessible information regarding the certification status of the other solutions. Consequently, it is probable that these remaining solutions are categorized as wellness and well-being devices.

The forthcoming sections will elucidate the prospective certification process for the in-development version of the Clynx® Platform, through QMS and TD assessment.

## 3.2 Qualification as a medical device

The Qualification as an MD specifies the characteristics of the device which make it compliant with the MD definition on the MDR, including its intended purpose, intended user groups, and the context of use [5]. With this understanding and taking into account all the features of the new version of the Clynx® Platform, the intended purpose of the Clynx® Platform will be as presented in Fig. 5.

**Fig. 5** Intended purpose, which will be included in the Intended Use File in the new version of the Clynx® Platform's TD. Image obtained from Clynx® Health

4. Intended Purpose

4.1. Summary Intended Purpose

Clynx Platform is a software intended to be used in the functional exercising sessions within physical and cognitive rehabilitation.

It is to be configured by healthcare professionals in a clinical environment and used by lay people autonomously at home environment.

It is intended to be used as a complementary tool for exercise, and it might be used by patients only when their Healthcare Professional considers there is ability to exercise autonomously. It is not intended for diagnosis.

It is intended to perform quantitative measurements, to provide information for therapeutic purposes and to be used by health professionals as a support for decision on treatment plans adjustments.

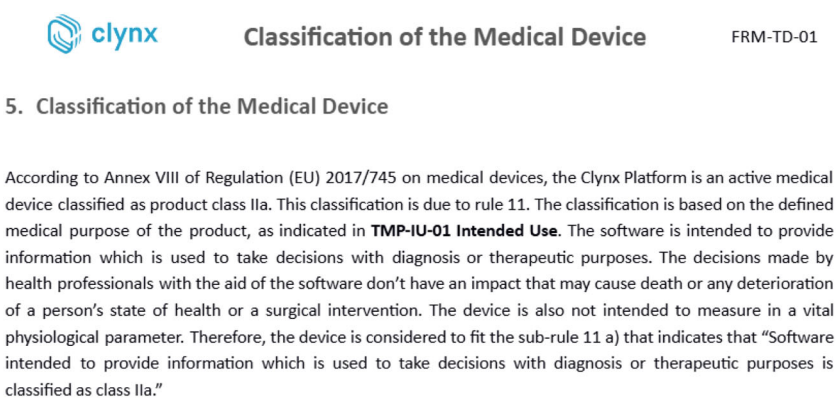
## 3.3 Classification

Considering the new Clynx® Platform's specified functions, such as real-time feedback, quantitative measurements, and clinical data collection, it will actively engage patients and records bio-kinetic data.

The software's purpose will include offering information to health professionals for therapeutic decisions. Importantly, decisions made by healthcare professionals with the software's assistance will not carry the risk of causing death, health deterioration, or necessitating surgical interventions. Additionally, the software will not be intended for vital physiological parameter measurements. Consequently, the device will align with **Sub-Rule 11(a)**, classifying it as **Class IIa**, as it will fall under *Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes* [5]. The text to be included in the new version of the Clynx® Platform's TD is presented in Fig. 6.

## 3.4 General and safety performance requirements

Considering the Clynx® Platform's future role in performing quantitative measurements as part of its Intended Use, it will qualify as a measuring device [5]. Consequently, adherence to the *Requirements for devices with a measuring function* (**Requirement 15**) will be vital. This requirement underscores the necessity for diagnostic and measuring devices to


clynx Classification of the Medical Device FRM-TD-01

5. Classification of the Medical Device

According to Annex VIII of Regulation (EU) 2017/745 on medical devices, the Clynx Platform is an active medical device classified as product class IIa. This classification is due to rule 11. The classification is based on the defined medical purpose of the product, as indicated in **TMP-IU-01 Intended Use**. The software is intended to provide information which is used to take decisions with diagnosis or therapeutic purposes. The decisions made by health professionals with the aid of the software don't have an impact that may cause death or any deterioration of a person's state of health or a surgical intervention. The device is also not intended to measure in a vital physiological parameter. Therefore, the device is considered to fit the sub-rule 11 a) that indicates that "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa."

**Fig. 6** Classification of the medical device justification, which will be included in the Classification File in the Clynx® Platform's TD. Image obtained from Clynx® Health

be meticulously designed and manufactured to ensure accuracy, precision, and stability that align with their intended purpose. This requires the application of robust scientific and technical methodologies, with Clynx® Health clearly specifying accuracy limits [5]. The text included in Clynx® Platform's TD will be presented in Fig. 7.

Therefore, **Requirement 15** mandates evidence from tests that assess the accuracy, precision, and stability of the quantitative measurements conducted by the software [5, 12]. These clinical studies will be an integral part of the device's Clinical Evaluation.

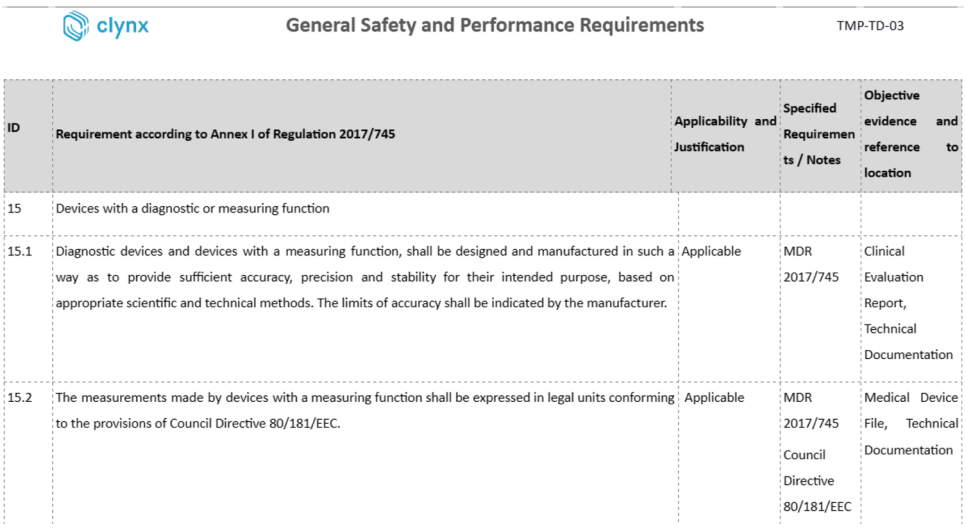
### 3.5 Risk assessment

The risk management file of Clynx Platform was produced according to the guidelines presented in ISO/TR 24971:2020 [17] and ISO 14971:2019 [16] and has the following phases:

- *Risk Assessment* The process of assessing the risks related to the medical device by documenting reasonably foreseeable misuse, identifying hazards and hazardous situations, its causes and consequences, and estimating their risk combining the probability of occurrence of harm and possible severity of consequences.
- *Risk Evaluation* The determination of acceptability of estimated risks is done by applying a risk matrix to every risk identified and determining if it can be reduced by applying control measures or if the benefits outweigh the risks, and it can be considered an acceptable risk.
- *Risk Control* Application of control measures in order to reduce risks to its acceptability point by reducing the probability of occurrence or the severity of consequences.
- *Residual Risk Evaluation* Even after reducing risks to its acceptability point and applying risk control measures, there are still residual risks remaining which need to proceed to a benefit-risk analysis and, if the benefit does not outweigh the risk, control measures need to be applied.

### 3.6 Clinical evaluation: clinical evidence generation

Clinical Evaluation stands as a pivotal phase in securing CE marking, playing a crucial role in both showcasing and validating the performance of a medical device. The Clinical


clynx General Safety and Performance Requirements TMP-TD-03

| ID | Requirement according to Annex I of Regulation 2017/745 | Applicability and Justification | Specified Requirements / Notes | Objective evidence and reference to location |
|---|---|---|---|---|
| 15 | Devices with a diagnostic or measuring function | | | |
| 15.1 | Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer. | Applicable | MDR 2017/745 | Clinical Evaluation Report, Technical Documentation |
| 15.2 | The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC. | Applicable | MDR 2017/745 Council Directive 80/181/EEC | Medical Device File, Technical Documentation |

**Fig. 7** Requirement 15 which will be included in the GSPR File in the Clynx® Platform's TD. Image obtained from Clynx® Health


**Fig. 8** Clynx® Platform and Qualysis® camera systems set-up

Evaluation Plan (CEvP) serves as the blueprint for this process, demanding clear articulation of the medical device's clinical benefits and underscoring its significance in the healthcare market [5, 12]. This article only focuses on the first step of CEv, which is clinical evidence generation.

In an endeavour to meet these rigorous standards, Clynx® Health executed a clinical study, assessing both the usability and social, economic and environmental impact of telerehabilitation facilitated by the current version of the Clynx® Platform [9]. This study serves as an integral component of the Clinical Evaluation (CEv) for the medical device.

Looking ahead to the future Intended Use of the Clynx® Platform, the software is poised to function as a crucial auxiliary tool for healthcare professionals. Its role will be to empower them to craft tailored physical rehabilitation treatment plans that adapt to the evolving needs of each patient. Consequently, the inclusion of a performance claim, specifically related to quantitative measurements [12], becomes imperative; as "*Quantitatively measures body movement, including range of motion, reaction time, and covered distance from the start position, with a specified level of precision, accuracy, and stability, aiming for a minimum of 90% and ideally reaching 95%*". The incorporation of this quantitative measurements feature within the future Clynx® Platform software is of paramount importance, necessitating validation of its scientific robustness to ensure reliability in monitoring patient progress during physical rehabilitation and treatment plan adjustments [12]. Conforming to the specifications outlined in Requirement 15, a critical step involves the execution of technical performance validation, encompassing an evaluation of accuracy, precision, and stability of these measurements [12].

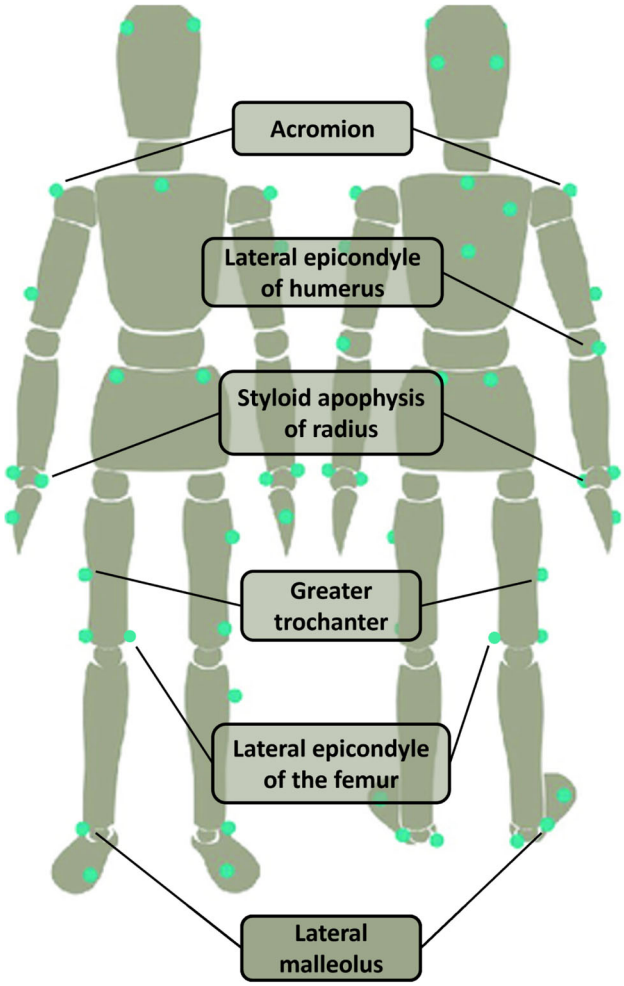



**Fig. 9** Qualysis® markers set-up. Obtained from [2]

For further clarity on the implementation of an experimental protocol within a clinical study for the Clynx® Platform CEv, please refer to the following section (cf. Section 3.6.1).

### 3.6.1 Experimental protocol for validation of technical performance: assessing range of motion accuracy, precision and stability in upper and lower limbs exercises

Clynx® Health is working in the scope of a validation protocol (Reference: 17/CES/2022) in partnership with Escola Superior de Saúde de Santa Maria. This project aims to build an experimental protocol for performing a comparative analysis between the established gold-standard motion capture system, Qualysis®[10], and the emerging Clynx® Platform in evaluating the Range of Motion (ROM) measurements' accuracy, precision and stability.

[10] To be consulted at: https://www.qualisys.com/

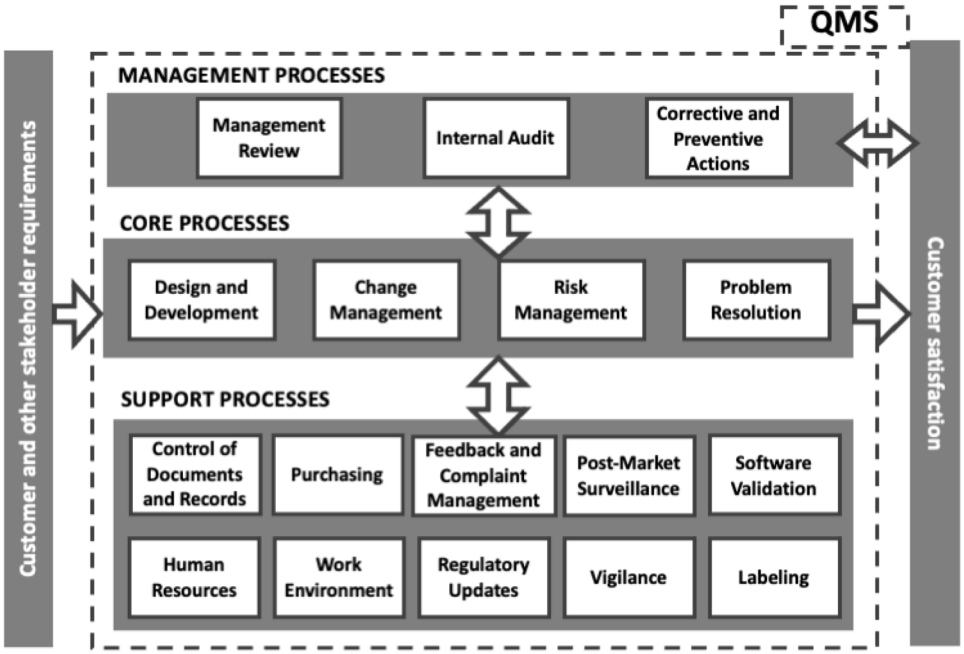



**Fig. 10** Quality Management System process map. Obtained from Clynx® Health

The study will involve healthy subjects participating in a simulated physiotherapy session at the Centro de Investigação para a Reabilitação, located at Escola Superior de Saúde do Instituto Politécnico do Porto. Crucially, every participant in the study will meet the inclusion criteria by confirming the absence of any prior history of lesions of the neurological, muscular or skeletal nature, the absence of pain during movement, and the absence of any prior musculoskeletal surgeries. The session plan will include two sets, with a rest period of 10 seconds, each consisting of seven repetitions of the following exercises: Shoulder Flexion/Extension, Shoulder Abduction/Adduction, Elbow Flexion/Extension, Shoulder Press, Hip Abduction/Adduction, Squat, March, and Seated Knee Flexion/Extension. The data collection setup is illustrated in Fig. 8.

The Clynx® Platform will employ two Astra S cameras operating at a frequency of 100 Hz. Positioned at a height of 86 cm above the floor, the subjects will stand 2.3 m away from the cameras, which will be spaced 25 cm apart and oriented towards the subjects. In the *Qualisys® Motion Capture System*, 3 infrared *miqus* M3 cameras and 8 *oqus* 500+

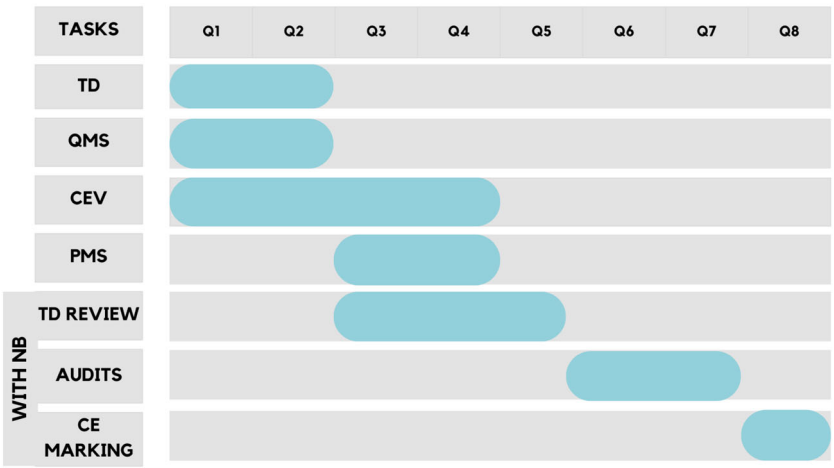



**Fig. 11** Gantt chart outlining a forecast for the certification process of the Clynx® Platform. The deadlines depicted in this figure are optimistic predictions based on the feedback received from the contacted NBs. This chart serves for illustrative purposes only

cameras will be employed, all operating at 100 Hz [10, 15]. Reflective markers will be arranged as depicted in Fig. 9.

During the session, concurrent recordings will be conducted: one capturing the ROM using the Clynx® Platform software, and another recording the 3D positions of markers through the Qualisys® system.

The subsequent data processing will involve algorithmic development. These algorithms will be utilized to convert the 3D positions obtained from the Qualisys® system into ROMs. Additionally, the algorithms will analyse the ROM data from both the Clynx® Platform and the Qualisys® system during the exercises performed by each participant.

To conduct a comparative analysis between the Clynx® Platform and Qualysis® ROM measurements (accuracy), and the Clynx® Platform data from different sets (precision) and from different cameras (stability), the agreement between the outputs of both sources will be evaluated. Two metrics are going to be employed, namely: the correlation coefficient, and the Bland-Altman test.

The correlation coefficient measures the linear association between two variables, ranging from +1 (complete positive correlation) through 0 (complete absence of correlation) to -1 (complete negative correlation). Positive correlation occurs when one variable increases as the other increases, while negative correlation is observed when one decreases as the other increases [18]. The Bland-Altman test involves studying the mean difference and constructing limits of agreement.

The Bland-Altman plot provides a simple means to assess bias in mean differences and estimate a 95% agreement interval [6, 7]. The accuracy, precision and stability values will be determined based on the relative error formula (cf. Eq. 1), where the true values are from Qualysis® and the observed ones are from the Clynx® Platform. All metrics will be implemented using Python algorithms.

$$1 - RelativeError = 1 - \frac{ObservedValue - TrueValue}{TrueValue} \tag{1}$$

### 3.7 Quality management system

In 2022, Clynx® Health initiated the establishment of its QMS to align with EN ISO 13485. This strategic move is a crucial step towards obtaining medical device certification and securing the CE marking for the Clynx® Platform.

Clynx® Health's QMS is organized into three categories: *Management Processes*, *Core Processes*, and *Support Processes* (cf. Fig. 10). These categories encompass various specific processes and associated supporting documentation, including the Quality Manual, Standard Operating Principles (SOP), and Technical Documentation. SOPs offer detailed step-by-step descriptions of each process, including their interconnections with other processes within the same category [8].

Clynx® Health proactively conducted an Internal Audit to assess its QMS in preparation for certification with NBs. This comprehensive remote audit, conducted by an independent external firm, focused on design and development, production, installation, and support services for the Clynx® Platform. The audit verified the compliance of the QMS with audit criteria and its ability to ensure compliance with regulatory requirements, contractual obligations, and expected outcomes. It also identified potential areas for improvement within the QMS.

The audit agenda covered Management Processes, Operational Processes, Resources Management Processes, Purchasing Processes, Improvements Management, and Regulatory Requirements. Some EN ISO 13485 requirements were deemed not applicable to the Clynx® Platform due to the nature of a medical software product.

## 4 Conclusion

This research aimed to provide a comprehensive guide on certifying software as a medical device by analysing European regulations, particularly the MDR 2017/745. This knowledge was applied to a case-study involving the Clynx® Platform.

The study successfully achieved its goal of offering a thorough understanding of certifying medical device software, including concepts, classification rules, safety requirements, Clinical Evaluation, and Technical Documentation. It also examined EN ISO 13485 requirements for Quality Management Systems. Based on the case study and the regulatory analysis, various materials were developed for the TD of the Clynx® Platform, which encompassed clinical studies, including an experimental protocol for a validation of technical performance clinical study.

The research's implications extend to all medical device software entering the European market, serving as a valuable resource for manufacturers.

The primary constraint in medical devices' certification is time. The process of certifying software as a medical device typically takes 1.5 to 3 years due to regulatory complexities, engagement with NBs, detailed documentation, and clinical studies. These time limitations suggest avenues for future research.

This includes evaluating exploring Post-Market Surveillance requirements, and conducting further clinical studies for the Clynx® Platform, namely the experimental protocol presented, including the fulfilment of the following steps of CEv. Then, the certification process can be initiated by submitting initial Technical Documentation to NBs. A Gantt chart predicting future work is presented in Fig. 11.

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## Declarations

**Conflicts of interest/Competing interests** Irina E. Lopes, Gonçalo Chambel and Joana Pinto are employed by Clynxio, Lda.. Carolina Clemente is an intern at Clynxio, Lda..

**Ethical approval** The experimental protocol presented on Section 3.6.1 was approved by the Ethics Committee of Escola Superior de Saúde de Santa Maria with the reference 17/CES/2022.



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