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Regulatory Study for EU MDR 2017/745 Certification of Thermal Medical Devices

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Abstract

This thesis examines the transition to Regulation (EU) 2017/745 on medical devices through an industrial case study in the spa medical device sector. The work concerns the verification, reorganisation and updating of the technical documentation of existing devices, rather than the design of an entirely new device, with the aim of supporting compliance with the new European regulatory framework.

The first part of the thesis presents Regulation (EU) 2017/745, explains its significance in relation to the previous directive-based system, and outlines its structure, implementation principles and main transitional periods. It then examines medical devices more generally, focusing on the regulatory definition, classification under Annex VIII and the product groups without an intended medical purpose covered by Annex XVI.

The second part addresses the Cico company case study and the two devices analysed in separate chapters: the IMT19 modular system for individual inhalation therapies and the VT16/VTH16 professional spa hydrotherapy tub. For these products, the thesis describes the documentation review conducted under the MDR, covering device description, intended purpose, risk management, clinical evaluation, post-market surveillance, vigilance and traceability. The discussion clearly distinguishes the IMT19 section, including its technical and therapeutic principles, from the section on VT16/VTH16.

An original contribution is the integration of two additional spa treatments into the IMT19 technical file: endotympanic insufflation and gingival irrigation. The analysis relates the technical and clinical plausibility of these applications to the documentation implications of extending the intended purpose, including claimed performance, risk analysis, instructions for use, clinical evaluation and PMS/PMCF activities.

The thesis concludes by proposing an operational pathway for achieving and maintaining MDR compliance, organised around gap analysis, verification and validation planning, traceability and life cycle management. The tests described are methodological proposals and are presented as activities to be planned, without attributing experimental results to the internship that were not actually produced.

Overall, the work shows that technical documentation is a strategic tool for implementing the MDR and highlights the biomedical engineer's role within the company as a link between design, quality, regulatory affairs and product management throughout the life cycle.

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Introduction

The spa medical devices sector occupies a particular position within the biomedical landscape, since it is located at the intersection of technology, clinical practice, therapeutic tradition and regulatory requirements. In this context, devices are not only technical tools, but systems that must ensure safety, performance, hygiene, controllability of delivery parameters and consistency between declared function and real use. This need becomes even more evident when the product is used in thermal or rehabilitation contexts, in which the supply of thermal water, air, steam or specific mixtures must be rigorously documented also in terms of regulatory compliance.

In recent years, the transition from the European directive system to Regulation (EU) 2017/745 has had a profound impact on this scenario. The MDR changed the way the medical device is qualified, classified, evaluated and maintained on the market, strengthening the role of technical documentation, clinical evaluation, traceability and post-market surveillance. As a result, manufacturers of established devices that have been on the market for years have also found themselves in the need to review their technical dossiers in order to verify their alignment with the new regulatory framework.

This thesis is born in this context and is developed from the experience carried out at Cico, a company operating in the field of spa medical devices. The focus of the work was not the new design of a device, but the documentary review of existing products, with the aim of understanding what information, evidence and documentary links are needed to support MDR compliance. In this perspective, the technical file was considered not as a mere set of formal documents, but as the structured expression of the regulatory identity of the device.

The objectives of the thesis are five. The first is to reconstruct the regulatory framework, clarifying the meaning of the MDR, its transition periods and its structure. The second is to define the perimeter of medical devices, their classification system and the extension of the discipline to groups of products without medical purposes. The third is to describe the business case and the work of reviewing the technical documentation carried out on real thermal devices. The fourth is to analyze an activity of particular application interest: the extension of the intended purpose of IMT19 to new spa treatments. The fifth is to translate the examined requirements into an operational adjustment path, with particular attention to gap analysis, verification planning, traceability and compliance maintenance.

From the methodological point of view, the work has developed through the reading of the European regulations and application sources, the analysis of the company technical file, the comparison between existing documentation and MDR requirements, and a targeted survey of the literature useful to support specific documentary choices. The approach adopted was therefore regulatory, technical and documentary. This approach faithfully reflects industrial practice, in which compliance is not limited to an abstract verification of requirements, but requires a continuous relationship between product, risk, intended purpose, claimed performance and available evidence.

The structure of the thesis reflects this path. The first chapter presents Regulation (EU) 2017/745.The second chapter deals with the definitions and classification of medical devices. The third chapter introduces the Cico business case and the method of document review adopted. The fourth chapter is dedicated to IMT19 and brings together description of the device, technical principles, therapeutic modules, literature support and MDR documentation review. The fifth chapter is dedicated to the VT16/VTH16 and contains technical descriptions, treatments that can be dispensed, document profile and MDR specificity of the professional spa hydrotherapy tub. The sixth chapter develops an operational path of adaptation and maintenance of compliance, applying it briefly to the two devices analyzed. The seventh chapter contains the conclusions, the limits of work and the main future developments.

Chapter 1

Regulation (EU) 2017/745

Regulation (EU) 2017/745, commonly referred to as the MDR (Medical Device Regulation), is the central reference for the discipline of medical devices in the European Union. It replaces the previous plant based on Directives 90/385/EEC and 93/42/EEC, introducing a legal framework directly applicable in the Member States and structured in a broader, more detailed and consistent manner with technological developments in the sector [1].

The MDR stems from the need to strengthen the level of protection of public health and to reduce the inhomogeneity of application that the system of directives had progressively highlighted. In a sector characterised by strong innovation, increasing digitisation, greater complexity of supply chains and the centrality of clinical evidence, the European legislator considered it necessary to overcome a model based mainly on initial placing on the market and to strengthen control of the device throughout its life cycle [1].

In the case of spa medical devices covered by this thesis, the regulation is of particular importance since it requires a review not only of the formal structure of the technical file, but also of the substantial consistency between intended purpose, claimed performance, risk management, clinical support, safety requirements and post-market processes. Understanding the regulation is therefore the essential prerequisite for correctly interpreting the document work developed in the company case examined.

1.1 General framework and transition to the MDR

Regulation (EU) 2017/745 was published in the Official Journal of the European Union on 5 May 2017 and entered into force on 25 May 2017 [1]. It amends Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009, and repeals Directives 90/385/EEC and 93/42/EEC. The transition from a directive to a regulation is not only formal: it implies direct and uniform application in the Member States, reducing the scope for national transposition and strengthening the homogeneity of the internal market.

The basic logic of the regulation is to consider the medical device as a product whose conformity must be justified not only before it is placed on the market, but also during its stay on the market. For this reason, the MDR attaches much greater weight than in the past to some key elements: clarity of intended purpose, risk-based classification, compliance with general safety and performance requirements, clinical evaluation, post-market surveillance, vigilance, traceability and control of economic operators.

This approach is also reflected in the strengthening of the role of notified bodies and in the way in which manufacturers have to build technical documentation. The latter is no longer a static collection of descriptions and certifications, but becomes the place where product descriptions, technical specifications, risk analysis, safety tests, clinical data, PMS plan, possible PMCF and traceability of changes must converge. In other words, the regulation shifts the centre of gravity of compliance from an essentially declarative logic to a continuous and documented demonstration logic.

For a company operating in the thermal field, this means that even devices with consolidated technology must be reinterpreted within a more structured scheme. The therapeutic indications, the operating parameters, the limits of use, the risk profiles, the management of sanitization and the consistency between technical documentation and clinical use become central aspects to support the legitimate permanence of the product on the market.

Transitional periods for the application of the Regulation

Transitional MDR rules have evolved significantly from the original plant. In the initial version of the Regulation, full application was expected from 26 May 2020. Following the COVID-19 pandemic emergency, Regulation (EU) 2020/561 postponed that date by one year to 26 May 2021 [2]. Since then, MDR has become the fully applicable regulatory framework for medical devices in the European Union.

However, the practical application of the Regulation has revealed structural difficulties, in particular related to the available capacity of notified bodies and the complexity of the transfer of numerous arrangements from the Directives to the new regulatory regime. In order to avoid interruptions in the availability of devices already placed on the market and still considered necessary, Regulation (EU) 2023/607 amended the transitional provisions of Article 120 of the MDR, extending the deadlines for certain categories of legacy devices and removing the so-called sell-off term [3, 4].

Extensions do not apply indiscriminately, but are subject to precise conditions. These include the absence of significant changes in design and intended purpose, the absence of unacceptable risks for patients and users, the adoption of a quality management system in accordance with the Regulation within the time limits and the effective start of the assessment process with a notified body [3, 5]. In other words, the transitional regime does not allow a simple passive postponement of the adjustment, but requires an active process of preparation for full MDR compliance.

As of today, the main deadlines to be considered are the following: for custom-made class III implantable devices, the transitional period is 26 May 2026; for class III devices and certain class IIb implantable devices, the deadline is 31 December 2027; for other class IIb devices, Class IIa devices and Class I devices requiring the intervention of a notified body, the transitional period is 31 December 2028 [3, 4]. The elimination of the previous final deadline for disposal of stocks also confirms the European legislator's desire to avoid the destruction of devices already lawfully placed on the market and still safe.

For the case study considered in this thesis, the transitional discipline has a very concrete impact. It justifies the need to undertake a structured document review already in the transition phase, without waiting for the final deadline. From an industrial point of view, in fact, the transitional time is useful only if it is used to build a coherent regulatory trajectory, able to link the current state of the technical file, gap with respect to the MDR and progressive updates of the evidence.

Structure of the Regulation: topics for chapters, articles and annexes

From a formal point of view, Regulation (EU) 2017/745 is a broad and articulated regulation. The original version contains 123 articles and 17 annexes, preceded by a set of introductory considerations explaining the rationale, objectives and principles of regulatory intervention [1]. To understand the meaning of the regulation it is useful to observe how the contents are distributed in the different chapters.

Chapter I defines the subject matter, scope and fundamental notions. Chapter II regulates the making available on the market, putting into service, the obligations of economic operators, the CE marking and free movement. Chapter III deals with identification and traceability of devices, registration of devices and economic operators, synthesis of safety and clinical performance, and EUDAMED. Chapter IV concerns notified bodies. Chapter V regulates classification and conformity assessment procedures. Chapter VI is dedicated to clinical evaluation and clinical investigations. Chapter VII deals with post-market surveillance, market surveillance and vigilance. Chapter VIII is devoted to cooperation between Member States, expert groups and registers. Chapter IX covers confidentiality, data protection, financing and sanctions. Chapter X contains the final provisions [1].

The annexes also have an essential function, because they contain the most operational part of the regulation. Annex I defines the general safety and performance requirements (GSPR). Annex II establishes the structure of the technical documentation. Annex III regulates the documentation relating to post-market surveillance. Annex VIII contains the classification rules. Annexes IX, X and XI define the main conformity assessment procedures. Finally, Annex XVI lists the product groups that are not intended for medical use falling within the scope of the Regulation [1].

For the work carried out in this thesis, the most relevant annexes are in particular Annex I, Annex II, Annex III and Annex VIII. They are in fact the core of the company document verification: the GSPRs represent the reference for the demonstration of safety and performance, Annexes II and III guide the reorganization of the technical file and of the PMS activities, while Annex VIII directs the classification and therefore the entire compliance path. The very structure of the Regulation

therefore shows that the MDR should not be read as a mere legal text, but as an integrated system of requirements, procedures and responsibilities.

1.2 Main regulatory references used in this study

For the specific objectives of this thesis, not all contents of the MDR have the same weight. The most widely used regulatory references are, firstly, Chapter I, because it contains the subject matter, scope and fundamental definitions, and Chapter II, which regulates the making available on the market and the obligations of economic operators, with particular attention to the role of the manufacturer. For the Cico case, Chapter V, on classification and conformity assessment, Chapter VI, on clinical evaluation and clinical investigations, and Chapter VII, on PMS, market surveillance and vigilance, are central.

At the level of individual provisions, the most relevant articles for this work are Article 2, because it defines medical device, accessory, active device, bespoke device and other key notions; Article 10, which clarifies the general obligations of the manufacturer; Article 61, relating to clinical evaluation; Articles 83–86, governing the post-market surveillance system; Articles 87–92, dedicated to vigilance; and Article 120, which is essential to understanding the transitional regime of legacy devices. In addition, at a time level, Regulation (EU) 2020/561, which postponed the general application of the MDR, and Regulation (EU) 2023/607, which redefined the transition periods for certain categories of devices.

As regards the annexes, those most directly used in this work are Annex I, which contains the general safety and performance requirements; Annex II, which structures the technical documentation; Annex III, which regulates the PMS documentation; and Annex VIII, which guides the classification of devices. Annex XVI has been considered primarily as a methodological reference for understanding the extension of the regulation to products without medical use, but it does not represent the core application of the Cico case. In summary, for this paper, the regulatory heart of the MDR consists of the combination of the requirements of Annex I, the document structure of Annexes II and III, the classification of Annex VIII and the transitional discipline of Article 120.

Chapter 2

Medical devices

Before addressing the specific case of the thermal devices analyzed, it is necessary to recall the normative definition of medical device and the system with which these products are classified. The notion of medical device is in fact particularly wide and includes very different products in terms of technology, invasiveness, duration of use, construction complexity and context of use. Proper product qualification is the first step towards identifying the applicable obligations and defining the technical file in a consistent manner.

2.1 Definition and classification of medical devices

Article 2 of the MDR defines a medical device any instrument, apparatus, equipment, software, implant, reagent, material or other article intended by the manufacturer to be used in humans for one or more specific medical purposes, including diagnosis, prevention, monitoring, forecasting, prognosis, treatment or attenuation of diseases, injuries or disabilities, as well as the study, replacement or modification of anatomy or of a physiological or pathological process [1]. The definition also clarifies that the product does not exercise the main action for which it is intended by pharmacological, immunological or metabolic means, although these may contribute to its function.

This definition highlights two essential elements. The first is the centrality of the intended purpose declared by the manufacturer: it is the latter, in fact, that determines the regulatory perimeter of the product. The second is the distinction from the medicinal product, based not so much on the shape of the product, but on the main mechanism of action. In practice, apparently similar products may fall under different regulatory regimes depending on the stated purpose and the way in which they produce their main effect.

In addition to the general definition, the Regulation introduces a number of specific types that have great application relevance. These include active devices, the functioning of which depends on a source of energy other than that generated by the human body or gravity; invasive devices that penetrate the body through an orifice or through the body surface; implantable devices intended to remain in the body after a clinical procedure; and custom-made devices,

manufactured on the basis of an individual prescription for a specific patient [1]. Software, where the manufacturer attributes a specific medical purpose to it, shall also be considered as a medical device for all purposes.

Additional relevant definitions concern accessories, i.e. products intended to enable compliant use or support the medical functionality of one or more specific devices, as well as procedural systems and kits, reusable surgical instruments and disposable devices. The MDR also attaches particular importance to the concept of intended purpose, as classification, type of evidence required, extension of risk assessment, labelling content and approach to clinical evaluation depend on it.

From a methodological point of view, definitions therefore play a fundamental role. An incomplete or ambiguous description of the device may lead to cascade errors in the classification, choice of compliance procedure, definition of required clinical data and construction of the technical file. For this reason, in regulatory practice, the definition of the product and its intended purpose is always the first step of document work.

Classification of devices according to Annex VIII

Annex VIII to Regulation (EU) 2017/745 lays down criteria for the classification of medical devices by risk [1]. The system is divided into four classes: Class I, Class IIa, Class IIb and Class III. Class I includes devices with the lowest risk profile, while Class III includes devices associated with the highest risk and generally requires the strictest level of control and involvement of the notified body.

The classification does not depend on the economic value of the product or its apparent complexity, but on the combination of several factors: duration of use, degree of invasiveness, anatomical location concerned, use of energy, contact with the patient, nature of the action carried out and criticality of the information provided by the device itself. The rules of Annex VIII are systematically organised and distinguish between non-invasive devices, invasive devices, active devices and special rules. The MDCG 2021-24, updated in 2026, provides further interpretative clarifications and confirms the importance of an approach consistent with the intended purpose and risk profile of the product [6].

From a practical point of view, classification is a decisive hub of the entire regulatory process. It determines the type of conformity assessment procedure, the degree of detail of the technical documentation, the level of clinical evidence required and the nature of the involvement of the notified body. Class I devices, except in special cases, may largely follow a self-certification path by the manufacturer. On the contrary, class IIa, IIb and III devices routinely require the intervention of a notified body and a deeper verification of conformity.

In the case of thermal devices analyzed in this thesis, classification is particularly important because it allows to define the level of in-depth analysis necessary in the technical dossier and in the demonstration of safety and performance. Classification influences, for example, the expected robustness of the link between declared performance and available data, the level of risk management

structuring and the relevance of post-market surveillance. It should therefore not be understood as a mere initial fulfilment, but as the starting point for the whole regulatory strategy of the device.

2.2 Products without a medical purpose and technical sources

One of the innovative elements of MDR is the extension of part of the discipline of medical devices to certain products that are not intended for medical use. Article 1 and Annex XVI to the Regulation cover certain product groups which, although not intended by the manufacturer for a clinical purpose, have operating procedures and risk profiles similar to those of medical devices for therapeutic or diagnostic purposes [1, 7]. This approach shows that the European legislator has adopted a risk-centered logic and not exclusively on the stated medical purpose.

The main groups of Annex XVI include: contact lenses or other articles intended to be introduced into or applied to the eye; products introduced into the human body by surgically invasive means to modify the anatomy or fix parts of the body, excluding tattoos and piercings; substances or combinations of substances used as fillers by subcutaneous, submucosal or intradermal injection; equipment intended for the reduction or destruction of fat tissue; devices that emit high intensity electromagnetic radiation, such as lasers and intense pulsed light for dermoaesthetic treatments; and equipment for brain stimulation with non-medical purposes [1, 7].

The inclusion of these products in the scope of the Regulation has two consequences. On the one hand, it requires manufacturers to apply safety, performance, conformity assessment and post-market surveillance requirements similar to those for medical devices. On the other hand, it requires an often non-trivial qualification and classification effort, as evidenced by MDCG Guide 2023-5 and the common specifications adopted by the Commission for the product groups of Annex XVI [7, 8, 9]. In this area too, the technical documentation plays a decisive role because it must clearly demonstrate how the product has been qualified, classified and referred to the applicable regulatory framework.

Although it does not directly address the spa medical devices examined in this thesis, Annex XVI is relevant from a methodological point of view. It confirms that European regulation increasingly tends to focus attention on risk profiles, user protection and the need for documented evidence, even when the product is not born with a traditional medical purpose. This general approach is consistent with the MDR approach and reinforces the centrality of documentation as a compliance governance tool.

MDCG and main technical standards for case study devices

Alongside the text of the Regulation, the work of qualification, classification and document review of the devices analysed was based on some particularly useful application references. Among the MDCG documents, the most important for the defining and classifying part is the

MDCG 2021-24 rev.1, which helps to interpret the rules of Annex VIII and to translate the intended purpose of the product into a correct class classification. The MDCG 2021-25, which clarifies how MDR requirements can be applied to legacy devices, is particularly relevant for the transition of devices already on the market. Finally, for the products of Annex XVI the main interpretative reference is MDCG 2023-5, useful above all to delimit what falls within and what does not fall within the scope of this work.

In terms of technical standards, the most important references for Cico devices are ISO 14971, used to structure the risk management process; IEC 60601-1, fundamental for basic safety and essential performance of electromedical devices; IEC 60601- 1-2, central for electromagnetic compatibility and for comparison with the state of the art; and UNI 10865, relevant for the specific context of thermal devices. For the purpose of this thesis, these standards are not treated as abstract references, but as concrete tools for reading the technical file: ISO 14971 guides the link between hazards, control measures and performance; IEC 60601-1 and IEC 60601-1-2 support the demonstration of safety and essential performance; UNI 10865 helps maintain the connection with the thermal context in which the devices are used.

In summary, for the specific case addressed in the thesis the really central references are: Article 2, Article 10, Article 61, Article 120, Annexes I, II, III and VIII, MDCG 2021-24 rev.1, MDCG 2021-25, ISO 14971, IEC 60601-1, IEC 60601-1-2 and UNI 10865. These are the references that, more than others, support the classification of devices, the organization of technical documentation, risk management, clinical evaluation and interpretation of the transitional regime in the transition to MDR.

Chapter 3

Company case study and documentation review method

The second part of the thesis focuses on the Cico business case, taken as a reference context to analyze in a concrete way the impact of MDR on spa medical devices already developed and used in practice. The interest of the case study lies not only in the specific nature of the thermal sector, but in the fact that it allows us to observe how the new regulation affects the management of existing products, with particular reference to the revision of the technical documentation.

In the business context considered, the main challenge was not the design of new platforms, but the review of consolidated devices to verify their alignment with the regulatory requirements currently required. This type of activity is emblematic of the transition to MDR: many companies, in fact, are confronted not so much with the conception of new technologies, but with the need to reinterpret in a regulatory key devices that, although technically mature, must now be supported by a more robust, integrated and coherent technical file.

3.1 Company context and relevance of the case study

Cico operates in the field of medical devices intended for the thermal and rehabilitation field. In this sector, the product is not limited to the machine alone, but is part of a therapeutic process that involves physical parameters, quality of the fluids used, delivery methods, dedicated accessories, sanitization procedures, maintenance activities and personnel trained to use. It follows that the technical documentation must describe not only the configuration of the device, but also its insertion in the real operating context.

From a regulatory point of view, the business context is characterized by the presence of devices born in a previous regulatory system and now subject to the need for realignment with respect to the MDR. This involves cross-checking the existing documentation, the requirements of Annex I and the structure of the technical file provided for in Annexes II and III. In a company of this type, the document work therefore assumes a strategic function: it connects the knowledge of the product, the experience

of use accumulated, the management of risks, the clinical support and the sustainability of stay on the market.

Relevance of case study

The choice to focus the analysis on Cico and these two devices responds to a precise logic. The case study allows to move from a theoretical level, based on the reading of the regulation, to an application level, in which the meaning of the MDR emerges through concrete problems of documentation, classification, product description, risk management and consistency of the indications of use.

The IMT19 and the VT16/VTH16 system also allow to examine the issue of adaptation to the M-DR from complementary perspectives. The two devices show how the document review must link the intended purpose, performance, risk and compliance within a coherent technical file. In both cases, the point of arrival is not an isolated change, but an overall strengthening of the technical file as a means of supporting compliance.

This part represents the core of the thesis work, because it describes the way in which the analyzed devices have been reviewed in terms of technical documentation from an MDR perspective. The activity carried out did not consist simply in the collection or storage of existing documents, but in a critical review of their internal consistency, their alignment with the requirements of the Regulation and their ability to support, as a whole, the demonstration of safety and performance of the device.

In operational terms, the document review was set as a structured gap analysis, developed by linking the available documentation with the logic of Annexes II and III of the MDR, with the general safety and performance requirements of Annex I and with the main relevant technical standards, in particular ISO 14971, IEC 60601-1, IEC 60601-1-2 and UNI 10865 [1, 10, 11, 12, 14]. This approach has made it possible to identify not only missing documents, but above all weak or incomplete links between the different sections of the technical file.

3.2 General documentation review method

The first step of the work consisted in mapping the documents available for each device. This mapping covered the general product description, technical specifications, functional schemes, instructions for use, risk analysis, test reports, clinical documentation, vigilance procedures, PMS documents and identification and traceability information. Once the documents were reviewed, they were compared with the expected structure of the MDR to verify completeness, updating and mutual consistency.

The review was not limited to a check on the presence/absence of documents. On the other hand, a horizontal consistency check was carried out, i.e. the correspondence between the various sections of the dossier. For example, the intended purpose stated in the general description of the device was compared with that in the instructions for use, with the statements in the

commercial documentation and with the scope considered in the risk analysis and clinical evaluation. Similarly, the technical specifications have been compared with the declared performance and the risks arising from it under reasonably foreseeable conditions of use.

This method has made it clear that the main problem, in many cases, is not the total absence of information, but its fragmentation or the lack of an explicit link between technical information, performance and regulatory requirements. The document review according to MDR can therefore be described as an integration work, in which the added value consists not only in producing new documents, but in making existing documents readable and coherent.

Device description and technical specifications

A key section of the technical file is the description of the device and its specifications. In the case of the devices analyzed, this part of the work required a more rigorous clarification of the product configuration, its variants, its accessories, the links between subsystems and the limits of use. In a thermal context, the description cannot stop at the only electrical or mechanical identification of the system, but must also consider aspects related to the fluid circuit, the methods of dispensing, the management of sanitization and the relationship between technical configuration and therapeutic function.

The specific effects of this revision were then articulated in the chapters dedicated to the individual devices. In this way, the general description of the method remains distinct from the technical analysis of IMT19 and VT16/VTH16, avoiding the dispersion of product information into separate sections.

This activity is particularly important because the description of the device is the starting point for all other sections of the technical file. If the description is generic or incomplete, risk analysis, clinical evaluation, PMS plans and instructions for use will inevitably be weak or misaligned.

Intended purpose, indications and claimed performance

In the MDR the intended purpose has a central role, since it defines the regulatory perimeter within which the device is to be evaluated. For this reason, an essential part of the document review concerned the analysis of the consistency between product definition, therapeutic indications, reference population, environment of use, intended users and declared performance.

In the case of thermal devices, this activity is particularly delicate. In fact, the main risk is that the tradition of use of the device or the thermal context in which it operates suggest a wider range of applications than that actually supported by the technical documentation. The review therefore sought to distinguish clearly what the device is intended to do, what constitutes a documented performance and what instead belongs to the general therapeutic context but cannot be immediately translated into product claim.

This distinction is of considerable practical importance. Excessive use, not adequately supported by clinical evaluation and risk management, weakens compliance. On the contrary, a well-defined intended purpose makes it possible to build more solid links with technical documentation, risk assessment, safety tests and communication to the user.

Risk management and connection with performance

The review of the technical dossier highlighted the centrality of risk management as a link between safety and performance. In line with ISO 14971, the risk management process has been considered not as an isolated document, but as a structure that must consistently reflect the product description, its environment of use, its users, its performance and the data available after placing on the market [10].

For the devices examined, the main risk profiles include electrical, mechanical, thermal, microbiological, incorrect use, electromagnetic incompatibility and incorrect management of the fluids used in the treatment. The specific risks of the individual devices have been traced back to the dedicated chapters, so as to link each scenario to its technical architecture and declared performance.

A key point of the review was the link between risk and performance. A medical device is not only compliant when it reduces risks to an acceptable level, but when it does so without compromising the function for which it is intended. It follows that risk control measures must also be assessed against their impact on the declared therapeutic performance. In this perspective, risk management becomes the place where security and function are integrated and documented.

Clinical evaluation, PMS, PMCF, vigilance and traceability

MDR attaches great importance to clinical evaluation and post-market activities. For the devices analysed, the document review was aimed at verifying whether the available documentation was sufficient to consistently support the claimed performance, taking into account both the literature and the experience gained in the field. In this perspective, clinical evaluation was considered not as a mere descriptive document, but as the point where technical information and clinical data converge.

PMS and PMCF have also taken on particular importance. For long-established devices on the market, PMS is a crucial source of information on the actual performance of the product in operation, complaints, accidents, recurring non-compliances and the effectiveness of corrective actions. PMCF, when proportionate and applicable, allows instead to update the clinical knowledge base of the device and to confirm over time the benefit-risk balance. The document review showed that the MDR requires a greater structuring of these processes and a better link to the technical file.

Another aspect examined was vigilance. In the company, the internal MDR supervisory module is a significant example of how regulatory requirements are translated into the operational procedure. Its structure includes general data, device identification, event screening, serious incident assessment, causal link, reportability, timing, investigation, CAPA, possibly FSCA and closure of the case. This type of document has a value that goes beyond the single signal: it demonstrates the maturity of the quality system in managing the device even after it is placed on the market.

Traceability is another decisive factor. Device identification, version references, modification management, matching of labelling, manual and real product configuration are aspects that directly affect the robustness of the technical file. The review highlighted that, in the MDR context, even small mismatches between different documents can become significant regulatory criticalities.

3.3 Operational organisation of the documentation review

The method described in the previous sections may be traced back to a repeatable operating procedure. The aim is not only to verify that each document is present, but to check that the content is up-to-date, consistent with the actual configuration of the device and linked to regulatory requirements and other evidence in the file. In the work carried out, this principle was applied by considering the technical documentation as a system in which a modification of the intended purpose, of an accessory, of a declared performance or of a configuration may require the review of several documents at the same time.
Figure 3.1 summarises the adopted workflow. The starting point is the census of the available information; it follows the identification of the MDR requirement or the relevant technical standard, then the comparison between document status and expected status. The result of the comparison is not treated as a simple present/absent dichotomy, but as a gap to be qualified and transformed into a documented action. After the update, the horizontal consistency of the dossier should be reviewed in order to verify that the change does not lead to mismatches with IFU, risk analysis, GSPR, clinical evaluation, labelling or post-market activity.

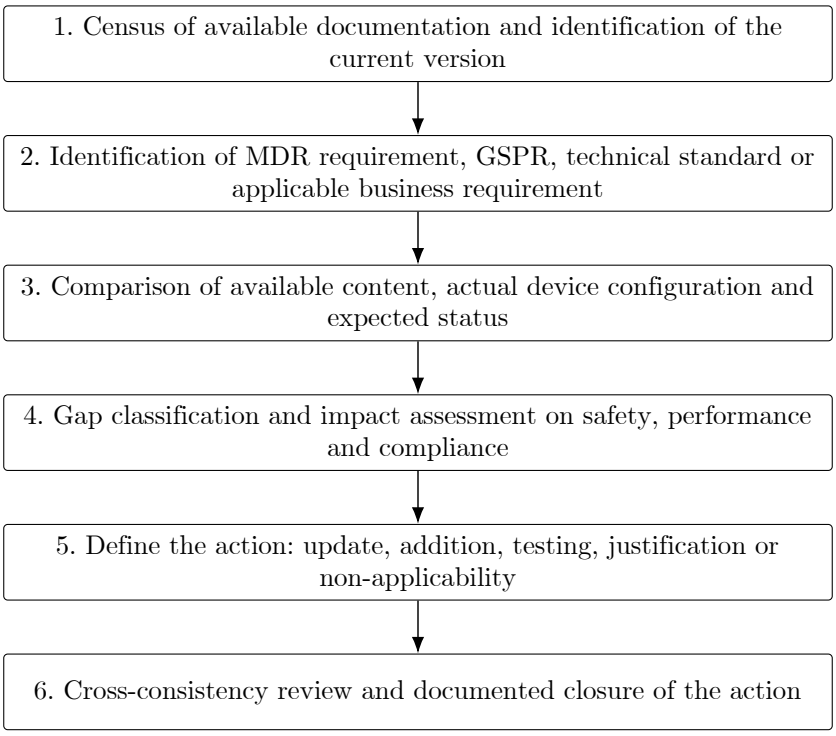


Figure 3.1: Operational flow of the document review applied to the case study.

The last step is particularly important in legacy devices, because information is often distributed in documents drafted at different times and according to pre-MDR logics. The review must therefore reconstruct a readable structure for the reviewer, highlighting the link between the product description, applicable requirements, risks, evidence and information provided to the user.

Document families and consistency checks

To make the review repeatable, the documentation can be organized for functional families. Table 3.1 shows the main controls that are useful in the case of the analysed devices. The table does not replace a GSPR checklist or quality plan, but clarifies which links must be verified during the review.

Table 3.1: Document families and main consistency checks.

Document category	Main checks
Device description and specifications	Models, variants, configurations, accessories, technical parameters, environment of use, lifetime and correspondence with the actual product.
Intended purpose and IFU	Consistency between intended purpose, expected population, users, indications, contraindications, warnings, performance and claim.
Risk management	Presence of relevant hazards, control measures, verification of the effectiveness of controls and link with post-market information.
GSPR and V&V	Applicability of requirements, compliance method, standards used, tests or justifications, and an unambiguous reference to the evidence.
Clinical evaluation	Consistency between claimed performance, clinical evidence, equivalence, data limits and PMCF plan.
Labels, UDI and traceability	Device identification, alignment with variants and packaging, symbols, versions and registration data.
PMS, PMCF, PSUR and vigilance	Consistency with the risk profile, data collection methods, trends, complaints, incidents, CAPA and technical file updates.

This organization allows you to distinguish two levels of control. The first is vertical and checks whether a document meets its specific requirement. The second is horizontal and checks whether the same information is reported consistently in the different documents. In the case of a modular device such as the IMT19, for example, the authorised configuration must be consistent with accessories, therapies, software and instructions; for the VT16/VTH16 the tank variant must be consistent with installed functions, loading/unloading modes, optional components and expected population.

Classification of gaps and closing criteria

To prevent gap analysis from turning into an indistinct list of tasks, it is useful to classify gaps according to the type of document problem. Four operational categories are considered in this work. A completeness gap concerns missing information or evidence; an update gap concerns an existing document but no longer aligned with the state of the art, the current configuration or the MDR; a consistency gap concerns discordant information between documents; a traceability gap concerns the absence of an explicit link between requirement, risk, test and evidence.

The closure of the gap must be defined in verifiable terms. It is not sufficient to indicate generically that a document has been 'updated': the amended version, the justification, the revised elements and, where relevant, the impact on the other documents. In this way the review becomes auditable and can be reconstructed even after a long time. From an organizational point of view, each action should include at least one manager, a priority, a deadline, the expected output and the criterion by which the action can be considered closed. Gaps that directly affect safety, essential performance, intended purpose or conformity assessment procedure normally require a higher priority than purely editorial corrections. Similarly, a gap that blocks multiple subsequent tasks, such as an unstabilized use destination or an undefined configuration, should be resolved before starting evidence or document updates dependent on that decision. This methodological approach is the link between the general method of Chapter 3 and the application path developed in Chapter 6. In the first case the focus is on how to read and critically review the existing file; in the second the same logic is used to plan the actions necessary to complete and maintain MDR compliance over time.

Chapter 4

IMT19: modular spa treatment system and MDR review

4.1 Overview of the IMT19 device

The IMT19 is a modular thermal device designed for individual inhalation therapies, framed as a class IIa device. The platform is designed to manage, depending on the configuration adopted, the use of thermal water, compressed air or steam in order to deliver inhaler treatments in a controlled and repeatable way. The modular nature of the system is particularly relevant from a documentary point of view, as it requires a precise description of which configurations are allowed, which accessories are associated with each treatment and which performance parameters must be maintained within defined limits.

From a technical point of view, the device is based on a set of subsystems aimed at fluid management, level control, recirculation, sanitization and the generation of the therapeutic mixture. In this context, the Venturi effect is an important functional element, as it allows fluids and gases to be combined in a manner consistent with the device's inhalation intended purpose. Apparently secondary aspects, such as waste management or liquid level control, also take on regulatory importance, because they can affect hygiene, repeatability of performance and user safety.

IMT19 is relevant to this thesis for three reasons. Firstly, the device represents a concrete example of thermal technology with defined therapeutic purposes. Secondly, its modularity requires particularly accurate documentation. Thirdly, it lends itself to the analysis of an extension of the intended purpose, such as endotympanic insufflation and gingival irrigation, which tests the consistency of the entire technical file.

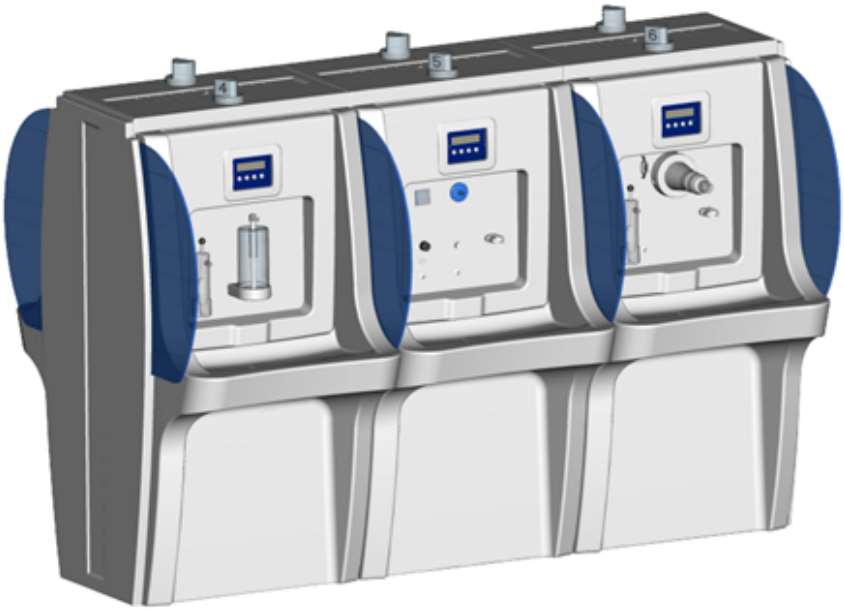


Figure 4.1: Overall view of the IMT19 system for individual inhalation therapies.

4.2 Technical principles and therapeutic modules of IMT19

Before analyzing the document review according to MDR, it is useful to describe the IMT19 from a technical and therapeutic point of view. This step makes it possible to clarify which treatments the device can deliver, through which physical vectors and according to which operating principles. This basis is important not only to understand the machine as an electromedical system, but also to correctly read the subsequent documentary choices on intended purpose, declared performance, accessories, risk analysis and clinical evaluation.

Technical architecture of IMT19

The IMT19 can be described as a class IIa modular electromedical thermal device, configurable according to the number of stations, the type of treatment and the management mode, manual or automatic. The platform is intended for the controlled delivery of individual thermal therapies using thermal water, compressed air and steam; in the case of medical aerosol alone, the system can also use prescribed water-soluble medicines, which are sprayed through a dedicated circuit.

From a constructive point of view, the device integrates hydraulic, pneumatic and electronic components. Internal circuits include interception, control and regulation elements of water and pneumatic vectors, while electronic management via cards and microprocessors allows you to set timing, sequences and delivery modes. Level sensors, timers, recirculation systems and sanitization procedures help to maintain continuity of service, uniform operating conditions and hygienic control of the circuit.

Each therapeutic station is modular and can be set up with specific accessories for the selected treatment. This modularity is a functional advantage, because it allows you to configure the system in a way consistent with the number of users and the type of therapy required, but it also requires a very accurate technical description. For each configuration, compatible accessories, operating parameters, pressure and flow limits, conditions of use, cleaning modes and destination anatomical district must be clarified.

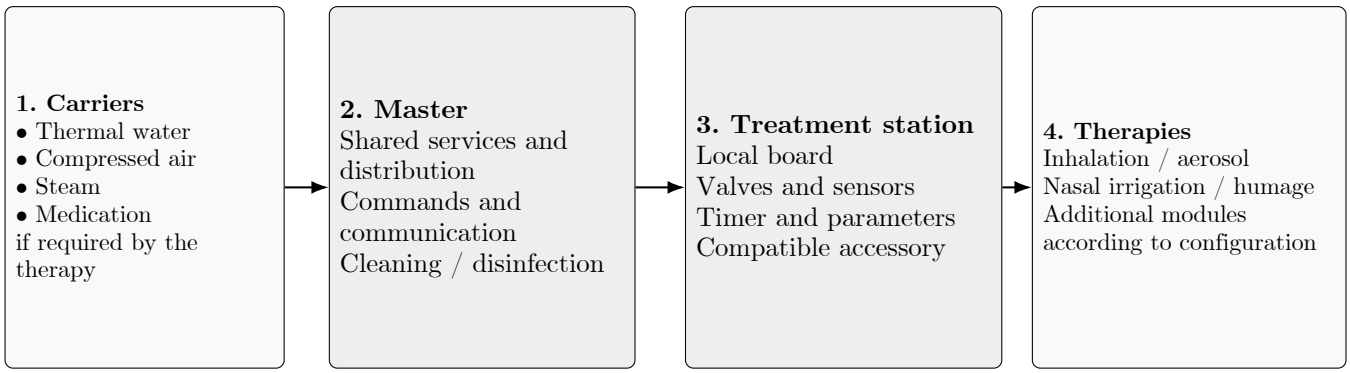


Figure 4.2: Functional architecture of IMT19: from the input carriers, through Master control and the configurable treatment station, to the therapy delivered.

Figure 4.2 shows that IMT19 is not a single delivery unit, but a platform that transforms and distributes different therapeutic vectors within configurable modules. This approach is also central from the MDR point of view, because it obliges to explain the relationship between the operating principle, the accessory used, the expected performance and the treated anatomical district.

Operating principle: Venturi effect and aerosol generation

The most important physical principle for many treatments provided by IMT19 is the Venturi effect. The device can be interpreted as a dynamic mixing system: compressed air or steam pass through a nozzle, increase their speed and generate a local depression capable of sucking thermal water. In this way the liquid is dragged, mixed with the vector and fragmented into drops or transformed into a hot-humid mixture, depending on the configuration selected.

The first relevant physical link is the continuity relationship:

$$Q = A \cdot v \tag{4.1}$$

where Q is the flow rate, A is the cross-sectional flow area and v is the fluid velocity. In a nozzle, reducing the cross-sectional area increases the carrier velocity. This is associated with Bernoulli's equation:

$$p + \frac{1}{2}\rho v^2 + \rho g h = \text{constant} \tag{4.2}$$

where p is the static pressure, ϱ the density of the fluid, v the speed and h the geometrical dimension. In the narrow area of the nozzle, the increase in speed leads to a decrease in static pressure; the resulting depression allows to suck up the thermal water and to fragment it into particles. In the case of real applications of the IMT19, the final distribution of the particles depends on the geometry of the nozzle, the pressure of the vector, the temperature, the accessory used and the specific therapy set.

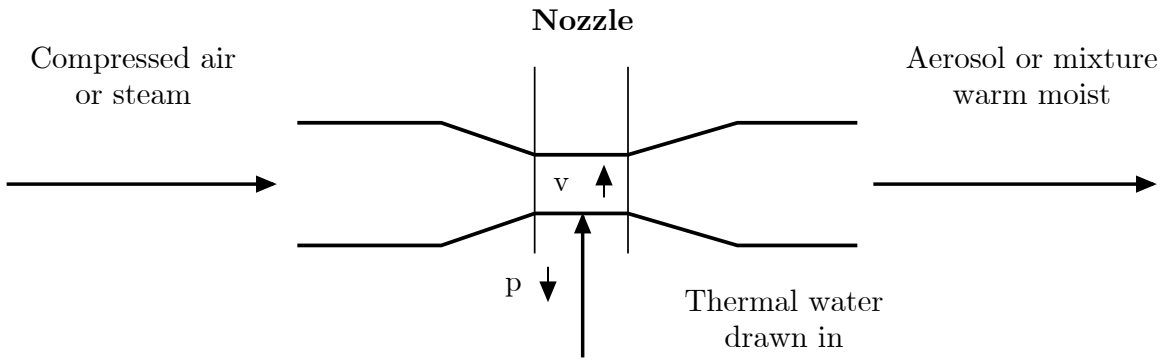


Figure 4.3: Simplified scheme of the Venturi effect used for the generation of the therapeutic mixture.

Figure 4.3 shows in schematic form the mechanism that connects fluid dynamics and therapeutic performance. In hot-humid inhalations the prevailing vector is steam and the mixture produced is oriented mainly to the upper airways; in the thermal aerosol the prevailing vector is compressed air and finer particles are obtained, destined to a deeper reach of the respiratory district. According to the data contained in the company's technical file, the most interesting granulometric references are between 10 and 100 µm for hot-humid inhalation, between 2 and 10 µm for thermal aerosol and with MMAD greater than 18 µm for micronized nasal shower. These values should be read as functional ranges of the described configuration, not as abstract parameters separated from the accessory and the mode of use.

Therapeutic modules available on IMT19

The IMT19 is designed to support different treatments through the same platform. The therapies are distinguished by main vector, technical principle of delivery and target anatomical district. Precisely this plurality of treatments requires that the technical file accurately identifies the relationship between machine configuration, accessories, operating parameters and intended clinical use.

Table 4.1: Summary of the main configurable therapies on IMT19.

Therapy	Carrier	Main technical principle	Target region
Warm moist inhalation	Steam	Venturi mixing of steam and thermal water	Upper airways, trachea, main bronchi
Thermal aerosol	Compressed air	Nebulisation in an aerosol chamber	Upper and lower airways
Sonic or vibratory aerosol	Compressed air + vibration	Aerosol with particle oscillation of approximately 100 Hz	Nasal cavities, paranasal sinuses; Eustachian tube ventilation
Ionic aerosol	Compressed air + ionization	Negatively charged aerosol particles	Airways
Micronised nasal irrigation	Compressed air	Large droplets, MMAD $>$ 18 µm	Nasal cavities and paranasal sinuses
Humage	Compressed air / thermal gas	Bubbling through thermal water to extract natural gases	Airways and ENT region
Medication aerosol	Compressed air	Nebulisation of prescribed water-soluble medications	Variable depending on the drug
Nasal Irrigation	Continuous flow of thermal water	Continuous irrigation, mainly through mechanical action	Nasal cavities
Endotympanic insufflation	Thermal gas	Gas obtained by bubbling through sulphurous thermal water	Eustachian tube and middle ear
Gingival irrigation	Thermal water	Low pressure local jet	Gingiva and oral mucosa

The table shows that the same device provides treatments united by the use of thermal water, but differentiated by physical logic and clinical objective. Inhalation, aerosols and medical aerosols are united by the central role of nebulization; nasal shower and irrigation instead enhance the mechanical washing of the nasal cavity; humage and endotympanic insufflation exploit the gas component; finally, the gingival irrigation introduces a local application of the water jet to the oral cavity. In documentary terms, this implies that it is not sufficient to list generically the available treatments: it is necessary to describe how each treatment is obtained, with which accessories and to which anatomical district.

The scientific rationale common to the thermal treatments of IMT19 can be traced back to three levels. The first is mechanical and concerns humidification, washing, mobilization of secretions and controlled delivery to the anatomical district of interest. The second is physical, because temperature, pressure, flow rate, particle size and duration of exposure affect the distribution of treatment. The third is chemical-biological and depends on the composition of the thermal water. In the case of sulphurous waters, the literature attributes part of the biological effects to the presence of sulfur compounds, in particular hydrogen sulphide, which at low concentrations is described as a biological mediator, while at high concentrations it can be toxic [15]. For this reason, in the technical file the reference to literature must always be linked to controllable parameters of the device, water quality, exposure mode and safety limits.

4.3 Additional therapies and supporting literature

The introduction of endotympanic insufflation and gingival irrigation expands the therapeutic field of IMT19 beyond the traditional perimeter of inhalation and irrigation treatments. From a

technical point of view, the two therapies require a more detailed description of the target district, dedicated accessories, dispensing parameters and contraindications. From the MDR point of view, this extension involves a coordinated update of intended purpose, declared performance, risk analysis, IFU and clinical support.

Endotympanic insufflation

Endotympanic insufflation was added as a therapy targeting the Eustachian tube and middle ear. Its technical principle is the use of gas obtained by bubbling through sulphurous thermal water and delivered through a dedicated accessory, catheter or nasal olive, to promote Eustachian tube patency and pressure balance between the middle ear and the external environment. In the technical file, this therapy is associated with conditions such as Eustachian tube dysfunction, secretory or serous otitis media, impaired middle ear ventilation, rhinogenic hearing loss and tubotympanitis. The most sensitive technical parameters are pressure, delivery duration, correct accessory positioning and patient suitability.

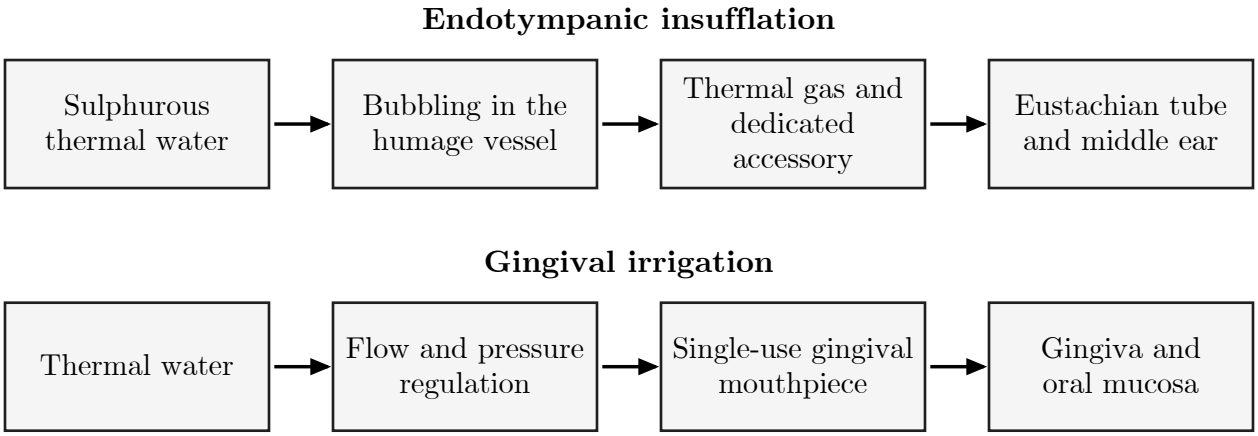


Figure 4.4: Simplified diagram of the two added therapies: endotympanic insufflation (top) and gingival irrigation (bottom).

The rational pathophysiology of endotympanic insufflation is based on the relationship between tubal ventilation, middle ear pressure and drainage of secretions. When the Eustachian tube does not ensure adequate functional communication between the nasopharyngeal and middle ear, negative pressure, endotympanic effusion and transmissive hearing loss may occur. Politzer and insufflation techniques aim to promote tubal opening, blood pressure rebalancing and drainage, through a controlled flow that must be compatible with patient anatomy, tolerability and safety [24, 26].

In terms of thermal literature, studies on inhaled treatments associated with Politzer or insufflation report favourable results in rhinogenic deafness and otitis media with effusion. Constantine et al. described, in subjects with chronic inflammatory processes of the upper airways and middle ear, audiometric improvements and reduction of hearing loss after a hot-humid inhalation cycle and Politzer with sulfur water [25]. Mesolella et al. reported tympanometric improvements after crenotherapy with jet inhalation and Politzer in children with Down syndrome and

otitis media with effusion, underlining the conservative, repeatable and well tolerated character of the approach [26].

The most direct support for endotympanic insufflation with thermal water comes from the study of Fermo et al., which analysed 74 paediatric patients with otitis media with effusion treated with thermal inhalation therapy associated with endotympanic insufflation. The authors observed significant improvements in tympanometrics, airborne auditory threshold and otoscopic framework, with an increasing share of normal tympanograms at follow-up; at the same time, the study concludes that the results, while favourable, require further confirmation in randomised and double-blind settings [23]. Consistent, but still preliminary, results are also reported in a number of adult cases with rhinogenic deafness treated with sulfur aerosol and bilateral tubal insufflations [28]. Finally, the pilot study of manosonic nebuliser in adults with otitis media with effusion supports the physical principle of aerosol associated with acoustic overpressure to modify tympanometric parameters, but concerns inhalers and not thermal water, so it should only be used as indirect support [27]. For IMT19, these sources support the clinical rationale of therapy, but require a prudent formulation of declared performance and subsequent post-market support.

Gingival irrigation

The gingival irrigation introduces a local application of the thermal water jet to the oral cavity. The treatment is performed through a dedicated, disposable gingival mouthpiece that directs a low pressure jet towards the gum margin and interdental spaces. The technical rationale combines mechanical cleansing, hydration of the mucosa and possible biological effect of thermal mineral waters. In the dossier, this therapy is associated with pictures such as gingivitis, periodontitis, stomatitis, glossitis and inflammatory conditions of the oral cavity. Also in this case the parameters of pressure, flow rate, time of application, hygiene of the accessory and methods of contact with the mucosa are essential elements of the technical description.

The closest clinical support to the gingival irrigation comes from the pilot study of Lopes et al., which compared sulfur thermal water and saline solution for 14 days in 90 subjects, observing a reduction in gingival bleeding, an improvement in certain periodontal parameters and a decrease in plaque, along with an improvement in quality of life related to oral mucosa diseases [29]. The level of evidence remains preliminary and the device studied does not coincide with IMT19, but the data support the clinical plausibility of the application. On a more mechanistic level, the meta-analysis of AlMoharib et al. on dental water jets also shows that oral jet irrigation can reduce plaque and gum bleeding compared to controls, even in a non-thermal context [30]. This reference does not demonstrate the effectiveness of the thermal gingival irrigation in the strict sense, but strengthens the physical rationality of the low pressure washing action.

Literature support for inhalation and irrigation therapies

For inhalation and irrigation therapies traditionally delivered by IMT19, the available literature suggests a favorable clinical rationale, but still heterogeneous. A narrative review published in 2025 included six Italian clinical trials for a total of 548 participants, reporting improvements in

mucociliary transport, reduction of symptoms and lower frequency or duration of recurrent respiratory infections after inhalations, aerosols and irrigations with different thermal waters. However, the authors themselves stress the strong heterogeneity of the protocols and the need for more standardised and international studies [16]. In paediatric patients, Franz et al. observed improvements in nasal obstruction, rhinorrhea, cough, sneezing and snoring after inhalation with sulfur-arsenic-ferruginous water, alone or associated with nasal irrigations, with good reported tolerability [17] in a retrospective study of 253 patients with recurrent upper respiratory disorders.

The previous literature also goes in the same direction, albeit with methodological limits. The systematic and meta-analysis of Keller et al. on the applications of thermal waters in upper respiratory pathologies has shown a potential clinical benefit of inhalation thermal therapies, but with studies often small and difficult to compare [22]. A 2023 meta-analysis of mineral water inhalation in bronchial asthma reported an improvement in FEV1 and a reduction in frequency and intensity of symptoms in patients with mild, moderate or partially controlled asthma, while reporting significant heterogeneity between the included studies [18]. From the MDR point of view, these data cannot be used as an automatic and conclusive evidence of the effectiveness of the individual device, but as an external support to be supplemented with technical description, delivery parameters and clinical evaluation plan.

For aerosol therapy, a prospective randomised 2019 study compared topical glucocorticoids with saline washes compared to dedicated inhaled aerosol therapy in patients with chronic rhinosinusitis, observing better subjective results in the aerosol group and endoscopic improvement in both groups. Again, the authors define the preliminary results and require confirmations on larger populations and longer protocols [19]. Although it does not directly cover thermal water and although it is not comparable to the IMT19, the study confirms that the aerosol dispense mode can significantly affect the outcomes perceived by the patient. At the preclinical level, the three-dimensional allergic nasal epithelial model proposed by Viegas et al. also shows that the duration and frequency of nebulisation are crucial for preserving epithelial integrity: short exposures of 1–2 minutes showed no toxic effects for up to three days, while longer and repeated exposures compromised the integrity of the model [20]. This fact reinforces the documentary importance of defining times, cycles and operating conditions.

For nasal irrigation, a prospective randomised, double-blind study from 2011 compared irrigations with sulphurous thermal water, salty, bromic, iodic and isotonic saline solution in 80 patients with chronic non-allergic rhinosinusitis. Both groups showed endoscopic and microbiological clinical improvement, while only irrigations with thermal water resulted in a significant reduction in total nasal resistance to rhinomanometry [21]. This data must also be interpreted with caution, but it is particularly useful to frame the clinical plausibility of irrigation treatments in a thermal context.

Overall, the available literature mainly supports the technical and clinical plausibility of the treatments provided by IMT19 and the reasonableness of their inclusion in the technical dossier, rather than a definitive demonstration of the effectiveness of the individual device in all its configurations. For this reason, the next part, dedicated to the MDR review, takes on particular importance: only by consistently translating these technical principles and these clinical references into the technical documentation can you build a robust regulatory justification for the intended purpose and declared performance.

4.4 MDR review of the IMT19 documentation

Overview of the work carried out

During the internship, the activity carried out did not involve a substantial modification of the entire technical documentation of the device, nor a complete revision of all the documents of the technical file MDR. The work focused mainly on the timely review of the specifications and description of the IMT19 device, with the aim of making the documentation more consistent, more identifying and more aligned with the structure required by Annex II of Regulation (EU) 2017/745.

The intervention concerned in particular certain sections of the IMT19 technical documentation: the general description and specifications of the device, the information provided by the manufacturer, the design and manufacturing information, the general safety and performance requirements and the setting of the risk analysis. The main objective was not to introduce significant design changes, but to clarify the document content and to ensure greater consistency between the technical file, user manual, labels, accessories, intended purpose and classification.

This activity is relevant in the MDR framework because the technical documentation must allow a precise understanding of the device, its intended purpose, its performance and documentary references to support compliance. Even when the device is already on the market as a legacy device, the transition to MDR requires reorganization of information and greater traceability between regulatory requirements, technical description and business documents.

In the case of IMT19, the main focus was on the alignment of the device to the correct name of "modular thermal system", on the revision of the intended purpose, on the distinction between accessories and components, on the classification according to Annex VIII and on the updating of the information provided by the manufacturer. In addition, the documentary effects resulting from the addition of two new therapies, endotympanic insufflation and gingival irrigation were considered.

Review of the general description and specifications of the device

The first work area covered the section dedicated to the general description and specifications of the IMT19.An initial point was the alignment of the commercial name of the device. The designation "inhalation therapy facility" was less representative than the actual functional perimeter of the device, since IMT19 is not limited exclusively to inhalation therapies. The term "modular thermal system" is more consistent with the structure of the device, with its configurability and with all the treatments provided.

This update has an important documentary impact. The name of the device appears in several sections of the technical file, in the information provided by the manufacturer, in the labels, in the user manual and in the references to accessories. Terminological alignment reduces the risk of inconsistencies and makes identification of the device more immediate.

A second intervention concerned the intended purpose. The formulation has been streamlined

with the aim of making it more identifying and more consistent with the real function of the device. In the MDR context, the intended purpose should clearly describe what the device is intended for, by whom it should be used, on what patient population and in what context. A use that is too broad or too general may make the relationship between declared performance, indications of use, clinical evaluation and risk management less clear.

Realignment of medical conditions in the device description and user manual was also considered. This point is particularly important because the medical conditions associated with treatments must be consistent throughout the documentation. If a pathology or condition is indicated in the technical description but not in the user manual, or vice versa, a discrepancy is created that can generate regulatory and practical ambiguity. Consistency between the technical file and user information is therefore an essential aspect of the review.

A further intervention involved the inclusion of a specific chapter dedicated to the functioning of the device and the medicinal substance to be inhaled in medical aerosol therapy. Medical aerosol differs from thermal therapies based exclusively on thermal water because it involves the use of specific water-soluble medicines, administered under medical prescription. The documentation must therefore clearly describe the operating principle, the role of the compressed air, the nebuliser used and the way in which the medicinal substance is aerosolised.

The review of the descriptive section also included realignment and differentiation between accessories and components. This distinction is important because the accessories are elements intended to allow or assist the medical use of the device, while the components are part of the internal or functional technical structure of the equipment. An unclear distinction can lead to problems in device description, classification, labelling, operating instructions and risk management.

Updating classification according to Annex VIII

A central point of the document activity concerned the classification of the device. The IMT19 was classified as a Class IIa electromedical device according to Regulation 12 of Annex VIII of Regulation (EU) 2017/745.The purpose of the review was to clarify the motivation for the classification and the relationship between device, accessories and contact with the patient.

Regulation 12 covers active devices intended to administer or exchange energy, substances or other elements with the human body, when such action takes place in a non-hazardous manner. In the case of IMT19, the device is active and allows the controlled delivery of thermal fluids, compressed air, steam, thermal gases or aerosolized medicines, depending on the selected therapy.

One aspect to be clarified in the classification is the non-invasive character of the device. The accessories used for the delivery of therapies come into contact with external surfaces of the body or with mucous membranes, but do not result in invasive penetration into the body according to the MDR classification logic. This clarification makes it possible to justify the framing of the IMT19 as an active non-invasive Class IIa device in accordance with Rule 12.

Classification is not a purely formal element. It shall determine the conformity assessment

procedure, the structure of the technical file and the level of documentary evidence required. For this reason, in the technical documentation it is important to report not only the class of the device, but also the rationale that leads to this classification.

The review of the classification has also been linked to the need to correctly distinguish accessories and components. Patient contact accessories should be described consistently throughout the documentation, because the type of contact affects risk assessment, hygiene, instructions for use and justification of classification.

Review of the information provided by the manufacturer

The second working area covered the information provided by the manufacturer. This part of the documentation is particularly important because it includes labels, instructions for use, symbols, device identification, UDI and information necessary for safe use.

A first activity concerned the specification of the countries of sale of the device, in particular Italy and Spain. This is relevant because the information provided by the manufacturer must be in the languages accepted by the Member States in which the device is intended to be placed on the market. The definition of the countries of sale therefore makes it possible to establish applicable linguistic and documentary requirements.

The introduction of the "Medical Device" symbol on labels was also considered in accordance with ISO 15223-1:2021/Amd 1:2025 [13]. The use of harmonised or recognized symbols makes it possible to clarify and standardize the information on the device and the packaging. Labelling shall allow identification of the device, manufacturer and information relevant to safety and performance.

Another review point concerned the preparation of a series of labels applicable to the device, different levels of packaging and accessories. Coherence of labelling is essential because the device and its associated elements must be able to be correctly identified throughout the supply, installation, use and maintenance chain.

The implementation of the UDI carrier, including UDI-DI and UDI-PI, was also considered. UDI enables unique device identification and is one of the central elements introduced by MDR to improve traceability, market surveillance and post-market information management. The presence of the UDI carrier on the labels must be consistent with the device data and the expected packaging levels.

References to the previous MDD Directive to be replaced by references to Regulation (EU) 2017/745 have been identified in the user manual. This activity is important because the documentation intended for the user must reflect the current regulatory framework. Maintaining outdated references to MDD could generate documentary inconsistency with respect to MDR evaluation.

The information provided by the manufacturer should also specify the intended purpose, user profile and target patient population of the device. In the case of IMT19, the device is intended for use by properly trained professional staff, in the thermal or clinical

field. The patient population should be described in a manner consistent with the intended therapies and indications in the manual.

Finally, the review considered the identification of expected clinical benefits, device performance and sanitation cycles. These elements directly link the information provided by the manufacturer to the safety and performance of the device. The sanitization cycles are particularly relevant for a spa, as the device uses thermal water circuits and accessories that require adequate hygiene measures.

Review of design and manufacturing information

The third working area covered design and manufacturing information. In the case of IMT19, the device must be treated as a legacy device certified according to MDD and evaluated in the MDR context. This condition makes it important to highlight the changes made compared to the legacy version of the device, especially in relation to the addition of new therapies.

Changes related to endotympanic insufflation and gingival irrigation should not be interpreted as simple descriptive additions. From a documentary point of view, it is necessary to indicate which elements of the design or configuration of the device are affected. This may include accessories, delivery modes, operating parameters, instructions for use, clinical indications and associated risks.

The design section must therefore allow to reconstruct the relationship between the legacy device and the MDR-rated version. In particular, the changes introduced, their rationale, their impact on the intended purpose and the way in which those changes have been reflected in the technical file should be clarified.

As far as manufacturing is concerned, the business included the need to bring critical and non-critical suppliers back in an orderly manner. Critical suppliers are those whose components, processes or services can affect the quality, safety or performance of the finished device. Their identification is important for the quality system and for the traceability of production.

The definition of the sites where the design and production phases take place was also considered. This information is relevant because the technical file must make it possible to understand where the main activities are carried out and how they are controlled. In the MDR framework, manufacturing is not only about the physical production of the device, but also about process control, supplier qualification, traceability and consistency with the quality management system.

Review of general safety and performance requirements

Another area of activity covered the general safety and performance requirements, GSPR. The GSPR analysis shall be integrated in accordance with Annex II, point 4 of Regulation (EU) 2017/745.

This means that the technical documentation must indicate which requirements are applicable, how they have been met and what documentary evidence supports compliance.

The revision is not limited to the compilation of a checklist. For each applicable requirement, it is necessary to provide a rationale or justification, indicate any technical standards used, report available evidence and link the requirement to the documents in the technical file. In this way, the GSPR checklist becomes a traceability tool and not just a compliance list.

In the case of IMT19, the general safety and performance requirements must be linked to different aspects of the device: electrical safety, mechanical safety, materials, accessories, patient contact, usability, manufacturer information, performance, hygiene and sanitation. The presence of thermal water, compressed air, steam, thermal gases and aerosolised medicines requires particular attention to the consistency between declared performance and risk control measures.

The demonstration of compliance with the Regulation shall include three main elements: justification, validation and reference to the technical documentation files. The justification explains why a requirement is applicable or not applicable and how it is met. Validation shows that the solutions adopted are adequate. The reference to the files allows you to quickly trace the documentary evidence.

This approach is consistent with the MDR logic that the technical file must allow an auditor or a notified body to follow the logical path linking requirement, evidence and conclusion of conformity.

Updating the risk analysis approach

The last area considered concerns risk analysis. Risk management must be set according to the CEI UNI EN ISO 14971/A11:2022 standard, which represents the reference for the application of risk management to medical devices in the European context.

For IMT19, risk analysis should take into account the characteristics of the device and the treatments that can be delivered. The hazards may concern electrical, thermal, mechanical, hygienic, functional aspects, usage errors, malfunctions, accessories, pressure, temperature, contact with mucous membranes or external surfaces and sanitization procedures.

The review of the risk analysis must be linked to the documentary changes introduced. The addition of endotympanic insufflation and gingival irrigation requires checking whether new hazards are present or whether certain risks already considered should be reassessed. For endotympanic insufflation, particular attention should be paid to pressure control, patient suitability, use of the accessory and correct application of therapy. For the gingival irrigation, the pressure and flow rate of the jet are relevant, hygiene of the accessories, contact with the oral cavity and correct use by the operator.

Risk control measures may result from design, material selection, operating limits, dedicated accessories, warnings, operating instructions, cleaning procedures and maintenance activities. It is essential that these measures are consistent with the rest of the

documentation. If a risk is controlled by information to the user, this information must be included in the manual. If a risk is controlled by sanitization, the sanitization cycle must be clearly described.

Risk analysis must also maintain a link with PMS and vigilance. Any complaints, incidents, malfunctions or feedback from the market must be able to be used to update risk management and confirm the acceptability of residual risks.

Product verification and validation

A further area considered in the document review concerns the verification and validation of the product. This part of the documentation is relevant because it demonstrates, through objective evidence, that the device meets the applicable requirements and that the declared performance is supported by appropriate evidence.

In the case of IMT19, verification and validation activities must be planned taking into account both the regulatory state of the art and the changes introduced with the addition of new therapies. External testing laboratories shall be accredited in accordance with ISO/IEC 17025 to ensure technical competence, impartiality and reliability of test results.

Key verifications include electrical safety and electromagnetic compatibility tests. Since IMT19 is an electromedical device, these verifications must be updated to the applicable regulatory state of the art, referring to the IEC/EN 60601 series and its updates. In particular, the documentation must take into account requirements relating to fundamental safety, essential performance and electromagnetic compatibility, including any updates introduced by the most recent amendments.

Biocompatibility testing according to the EN ISO 10993 series should also be considered. This is especially relevant for accessories or parts that come into contact with the patient, even when the contact concerns external surfaces or mucous membranes. The biological assessment shall be consistent with the type and duration of contact, the materials used and the intended purpose of the device and its accessories.

Another important element concerns the sanitization process. IMT19 integrates washing and sanitizing cycles of pipes and the parties involved in the delivery of therapies. Since sanitization is a hygienic and microbiological risk control measure, the process must be validated. Validation shall demonstrate that the intended cycle is effective, repeatable and adequate compared to the use of the device in a thermal environment.

At the date of the activity, these tests are not yet performed, since the implementation of the two new therapies, endotympanic insufflation and gingival irrigation, is not yet completed. As a result, verifications and validations can only be completed after the final definition of the

Software must also be considered in the verification and validation documentation. According to IEC 62304, it is necessary to clearly identify the software used, including name, model or denomination, version, function performed and expected connections, including any connections to external servers or systems. In the case of IMT19, the software is connected to the management of care places, the selection of therapies, the delivery times, the sanitization and, when provided, the connection with a remote Personal Computer.

Software documentation must include verification of software requirements, SRS, Software Requirements Specification, and software design, SDS, Software Design Specification. The SRS allows you to define what the software must do, while the SDS describes how these requirements are implemented at the design level. Consistency between requirements, design, verification and real operation is essential to demonstrate that the software contributes in a controlled manner to the safety and performance of the device.

Finally, cybersecurity aspects must also be evaluated. Since the device can provide communications with external computer systems or with a remote Personal Computer, it is necessary to consider risks related to unauthorized access, data alteration, loss of system availability, integrity of configurations and protection of information. Cybersecurity must be treated as part of device risk and security management, especially when software or connections can affect the delivery of therapies or data recording.

The verification and validation section is therefore a link between design, testing, software, security, performance and risk management. In the work carried out, it was set as a task to be completed after the completion of the implementation of the new therapies, constituting a future development necessary to consolidate the technical documentation of IMT19.

Post-market surveillance under Annex III

The document review also considered aspects related to Annex III of Regulation (EU) 2017/745, concerning the technical documentation on post-market surveillance. In the case of IMT19, this part does not concern experimental tests or physical modifications of the device, but rather the setting of the documentation necessary to monitor the device after obtaining the CE marking according to MDR.

post-market surveillance is an essential tool to keep the device's evaluation up-to-date during its life cycle. Through PMS and PMCF, the manufacturer collects and analyzes information from the real-life experience, with the aim of confirming safety and performance, identifying emerging risks, verifying the acceptability of the benefit-risk balance and updating, when necessary, the technical documentation.

Post-market surveillance plan

For IMT19, a new post-market surveillance plan must be drawn up for the years following the achievement of the CE marking according to MDR. The PMS plan must define in a structured way what data will be collected, how often, through which sources and with which internal responsibilities. It must also indicate how the data collected will be analyzed and how they can feed the update of clinical evaluation, risk management, instructions for use and, if necessary, corrective or preventive actions.

The plan shall include the general PMCF procedures and methods applicable to the device. These include the collection of clinical experience gained, analysis of user comments and feedback, review of updated scientific literature and consultation of other relevant clinical data sources. These activities are particularly important for a legacy device, because they allow you to confirm over time that the clinical and safety profile remains acceptable even after switching to MDR.

PMCF activities must be implemented and maintained continuously. For IMT19, this means collecting data on the therapies already present and, once the implementation is completed, also on the new treatments introduced, i.e. endotympanic insufflation and gingival irrigation. The aim is not necessarily to produce new experimental clinical trials, but to set up a documented and proportionate system to collect post-market clinical evidence and verify that no new risks or criticalities emerge.

The PMCF plan must also include a detailed and justified schedule of activities. This timetable must indicate when the data collection will be carried out, when the analyses will be carried out, when the reports will be drawn up and with what frequency the results will be reassessed by the manufacturer. Time planning shall be proportionate to the class of the device, its clinical history, the legacy nature of the product and the changes introduced in the intended purpose.

In the case of IMT19, continuity of clinical safety is a central point. The device is already present as a legacy device, but the extension of the intended purpose requires the PMCF to remain active and adequately updated. In particular, the data collected after the CE marking should make it possible to verify that the new treatments are used in the intended conditions, that there are no unidentified risks and that the clinical performance remains consistent with what is stated in the technical documentation.

Periodic safety update report

For Class IIa devices, the MDR also requires the preparation of the periodic safety update report, PSUR, in accordance with Article 86.The PSUR is intended to summarise the results and conclusions arising from post-market surveillance activities, providing an updated view of the safety and performance profile of the device.

In the case of IMT19, the PSUR shall include at least the conclusions of the benefit-risk assessment, the main findings of the PMS and PMCF, any trend analysis, information on

complaints or incidents, any corrective or preventive action taken and the sales volume of the device. The sales volume is important because it allows to correctly interpret the frequency of events, complaints or reports regarding the actual exposure of the device on the market.

The PSUR should also consider any updates resulting from the introduction of endotympanic insufflation and gingival irrigation. Once the new therapies are implemented and included in the final documentation, the PMS system will have to collect data distinguishing, where possible, the type of treatment performed. This distinction will allow to identify any specific critical issues associated with a single care and to update risk management in a more targeted way.

The preparation of the PSUR should not be interpreted as an isolated activity, but as part of a continuous system of updating the technical file. The PSUR conclusions may result in changes to clinical assessment, PMCF, risk analysis, instructions for use or vigilance activities. In this sense, post-market documentation represents a direct link between real experience of use and maintenance of MDR compliance.

In the work carried out during the internship, the activity related to Annex III was then set as a document review and planning. The new PMS plan and the future PSUR will have to be completed and maintained in the years following the CE marking, in order to ensure continuous monitoring of IMT19 and new therapies introduced.

EU declaration of conformity in accordance with Annex IV

A further documentary element considered concerns the EU Declaration of Conformity, as provided for in Annex IV of Regulation (EU) 2017/745.The declaration of conformity is the document by which the manufacturer certifies, on his own responsibility, that the medical device complies with the applicable requirements of the Regulation. It is therefore a conclusive document of the conformity assessment process, but must be consistent with all the information contained in the technical file.

Before placing a device on the market or putting it into service, the manufacturer shall carry out the conformity assessment of the device in accordance with one of the procedures laid down in Annexes IX to XI of the MDR. The choice of procedure depends on the risk class of the device, the type of product and the involvement of the notified body. In the case of IMT19, Class IIa electromedical device, Cico S.r.l. has chosen to proceed with the conformity assessment according to Annex IX, Part A, concerning the quality management system and the evaluation of technical documentation.

The declaration must contain the information necessary to uniquely identify the device. For the IMT19, trade name, intended purpose, catalogue number, REF code, serial number and any other elements useful for traceability must be reported. The inclusion of this data is essential because it allows the declaration to be linked to the device actually placed on the market and to the data in the labelling, UDI and technical file.

The risk class and the classification rule applied shall also be indicated. In the case of

IMT19, the documentation shall include Class IIa and Classification according to Rule 12 of Annex VIII MDR. This information shall be consistent with the classification rationale already set out in the general description of the device and in the technical documentation.

The declaration shall also include the name and identification number of the notified body involved in the MDR conformity assessment. The certificate issued by the notified body, together with the description of the conformity assessment procedure applied, shall also be provided. In the transition from MDD to MDD, this point is particularly important because the IMT19 had an EC certificate issued in accordance with Annex IV of Directive 93/42/EEC, while in the MDR path compliance is assessed according to the procedure chosen by the manufacturer in accordance with Regulation (EU) 2017/745.

Finally, the declaration must include the place and date of issue, the name and function of the person authorised to sign on behalf of the manufacturer and the signature thereof. These elements give formal validity to the document and identify the manufacturer's responsibility in the declaration of conformity.

From the point of view of the document review, the EU Declaration of Conformity should be seen as a summary document. It does not introduce new technical evidence, but recalls and consolidates the information contained in the technical file: identification of the device, intended purpose, classification, applied evaluation procedure, notified body, traceability and manufacturer responsibility. For this reason, any information in the declaration must be consistent with the user manual, labels, UDI, device description, classification and certification.

Clinical evaluation according to Annex XIV

The document review also included aspects related to clinical evaluation, governed by Article 61 and Annex XIV, Part A, of Regulation (EU) 2017/745. Clinical evaluation is the systematic process by which the manufacturer collects, evaluates and analyses relevant clinical data to demonstrate that the device meets the applicable general safety and performance requirements and that the benefit-risk balance remains acceptable throughout its life cycle.

In the case of IMT19, the clinical evaluation shall be in accordance with the Regulation specifying and justifying the level of clinical evidence necessary to demonstrate compliance with the applicable requirements of Annex I. This level of evidence shall be proportionate to the class of the device, the intended purpose, the nature of the legacy device, the clinical history of the product, the declared performance and the changes introduced by the addition of endotympanic insufflation and gingival irrigation.

Clinical evaluation plan

The clinical evaluation plan, CEP, Clinical Evaluation Plan, shall be drawn up in accordance with Article 61 and Annex XIV, Part A, of the MDR. The CEP shall define in advance the method by

which the manufacturer intends to collect, select, evaluate and analyse available clinical data. It is therefore not a generic descriptive document, but a methodological plan that must guide the subsequent drafting of the clinical evaluation report.

For IMT19, the CEP should identify the general safety and performance requirements to be supported by relevant clinical data. This link is important because it allows you to demonstrate in a traceable way which requirements of Annex I are supported by clinical evidence, such as preclinical or technical data and which from other documentary evidence.

The CEP should also describe in detail the expected clinical benefits for patients. These benefits should be linked to the intended purpose and the therapies provided by the device. For IMT19, the description of benefits must distinguish between treatments already provided, such as inhalation, aerosol, humage, nasal shower and irrigation, and new treatments introduced, i.e. endotympanic insufflation and gingival irrigation. This distinction is necessary because each treatment has different dispensing modes, anatomical district and clinical rationale.

The plan shall also update the activities planned by the manufacturer for the collection of evidence. These include data of equivalence with the legacy device, preclinical data from risk analysis, results of tests carried out or planned and the research protocol of scientific literature. The literature protocol should define consulted databases, keywords, inclusion and exclusion criteria, time period considered and method of critical evaluation of sources.

Demonstration of equivalence and legacy device

Clinical analysis may be based on the demonstration of equivalence between the clinically evaluated device and the legacy device, provided that such equivalence is adequately demonstrated and documented. In the case of IMT19, the reference to the legacy device is relevant because the product was already certified according to MDD and has a history of use in the thermal field.

However, equivalence cannot be considered automatically demonstrated. It must be evaluated on a technical, biological and clinical level. Technical equivalence covers features such as operating principle, configuration, materials, accessories, dispensing parameters and operating environment. Biological equivalence concerns materials and parts in contact with the patient. Clinical equivalence covers intended purpose, indications, patient population, expected benefits and safety profile.

According to the logic of Annex XIV, point 3, devices for which the full documentation necessary to demonstrate that equivalence cannot be considered equivalent shall not be available. This is particularly important when comparison is made with devices from other manufacturers or with devices for which complete information is not available. In the case of the legacy Cico device, equivalence can only be used more robustly if the available technical documentation demonstrates continuity between the legacy version and the MDR-rated device.

The addition of endotympanic insufflation and gingival irrigation requires a specific evaluation. Although the legacy device can support part of the clinical evaluation of existing treatments, the new therapies modify the perimeter of the intended purpose. Therefore, relevant clinical

evidence, technical data and specific risk assessments should be considered for such treatments.

Preclinical data, risk analysis and scientific literature

Clinical evaluation should also be linked to available preclinical data. For IMT19, this data may be derived from risk analysis, technical checks carried out or planned, safety tests, biocompatibility tests, sanitization validation and device performance documentation.

Non-clinical data do not replace clinical data, but help to support the safety and plausibility of declared performance. For example, the correct management of pressure, temperature, flow, materials and sanitization is relevant to demonstrate that the device can be safely used according to its intended purpose.

The research protocol of scientific literature plays a central role, especially for new treatments. For endotympanic insufflation, research should focus on evidence relating to the use of thermal gases, tubal functionality and relevant ENT treatments. For the gingival irrigation, research should cover oral irrigation, gingival treatments and thermal or odontostomatological applications consistent with the device. The selected sources must be critically evaluated in terms of relevance, methodological quality, population studied, outcomes and applicability to IMT19.

In the review carried out, the evidence of literature must therefore be organized for therapeutic families: respiratory inhalations and aerosols, nasal irrigations, humage and treatments with sulfur gas component, endotympanic insufflation and Politzer, gingival irrigation and balneotherapy/hydromassage applications for the VT16/VTH16. This classification allows to avoid generic citations and allows the CER to connect each source to the specific performance claimed, distinguishing between direct evidence on the treatment, indirect evidence on the physical principle of delivery and biological or preclinical support data [15, 17, 23, 29, 31].

Clinical evaluation report

The clinical evaluation report, CER, Clinical Evaluation Report, must collect and document the results of the analysis carried out according to the CEP. The CER shall describe the device, intended purpose, risk class, expected therapies, clinical data sources used, literature selection criteria, demonstration of equivalence, critical evaluation of data and conclusions on safety and performance.

For IMT19, the CER should clearly indicate what evidence supports existing treatments and what evidence supports new therapies. Endotympanic insufflation and gingival irrigation should not be treated as simple nominal extensions, but as treatments that require specific clinical rationale and a direct link to the updated intended purpose.

The CER should also contain the benefit-risk assessment. This assessment shall

complement clinical data, preclinical data, risk analysis results, any complaints or post-market data available and evidence limits. If some evidence is incomplete or indirect, the CER must clearly state this and justify any need for PMCF activities.

Update during the life cycle

Clinical evaluation is not a static document. CEP and CER should be updated throughout the life cycle of the device, using clinical data obtained through PMCF and post-market surveillance. This continuous update is particularly important for a legacy device undergoing MDR evaluation, because it allows to confirm the continuity of clinical safety and the acceptability of the benefit-risk balance over time.

In the case of IMT19, PMCF data should be used to confirm the clinical performance of existing therapies and, once implementation is completed, new treatments too. User comments, acquired clinical experience, updated literature, complaints, incidents and PMS data should be periodically evaluated and used to update the CER, risk management, IFUs and, if necessary, the PMCF plan.

In the work carried out during the internship, the clinical evaluation was considered as a documentary part to be realigned to the new MDR framework. The activity did not generate new experimental clinical data, but highlighted the need to update CEP and CER in a manner consistent with the updated intended purpose, with the available data on the legacy device, with the literature research protocol and with future PMCF activities.

Chapter 5

VT16/VTH16: professional spa hydrotherapy tub and MDR review

5.1 Technical and therapeutic overview of VT16/VTH16

The VT16/VTH16 system is a professional spa hydrotherapy tub for spa treatments, ozone therapy and balneotherapy. Unlike the IMT19, which focuses on the individual delivery of inhaler treatments, the VT16/VTH16 represents an equipment in which the electromedical component integrates closely with the management of the water/air circuit, with the pumping system and with the electronic operating controls.

The company's technical documentation describes the VT16/VTH16 as a Class IIa hydrotherapy tub, intended for use in thermal establishments and can only be used by properly trained professional personnel. The two models share the same functional logic, but respond to different operational needs: the VT16 is a traditional thermal bath for immersion treatments, while the VTH16 is configured for elderly, disabled or with reduced mobility, thanks to the presence of side door, internal handle and geometry designed to facilitate patient entry, placement and exit. In both cases, the maximum expected weight is 150 kg and the use in fragile patients requires supervision of the staff and authorization of the treating physician.

From the therapeutic point of view, the bath allows the execution of a simple bath, water whirlpool, bubbling bath, air / water whirlpool with ozone and chromotherapy. These functions should not be considered as nominal variants of the same treatment, because each involves a

Table 5.1: Summary of treatments and operating principles of VT16/VTH16.

Treatment	Technical principle	Relevant documentation aspects
Immersion bath	Immersion in thermal water, usually at 36–38 °C; duration defined by the doctor or operator.	Temperature and duration, water quality, patient condition and surveillance.
Water hydromassage	Recirculation by electric pump; air/water mixing for Venturi effect in the adjustable nozzles.	Flow/pressure, orientation of the jets, treated areas, skin integrity and mechanical risk.
Air bubble bath	Input of air through nozzles on the bottom, with bubble formation and gentler massage.	Air source, number of nozzles, intensity, comfort and hygienic control of the circuit.
Ozone therapy in the tub	Ozone generated and fed into the air/water circuit, then distributed in the tank through the nozzles.	Ozone generator and flow, exposure, ambient ventilation and maintenance.
Chromotherapy	Activation of RGB spots as a complementary function associated with the main treatments.	Information to the user, limits of claims and electrical/bright safety.

From a constructive point of view, the VT16 is made with a thermoformed body made of ABS/PMMA co-extruded material with fiberglass reinforcement, while the VTH16 is described as a gelcoat-coated fiberglass body. The configuration includes elements such as headrest, handles, footrest or side door, whirlpool nozzles, bubble bath nozzles, suction and discharge system, operator panel, air regulators, level and temperature sensors, electric pump, turbine or blower, ozone generator and, where applicable, automatic disinfection system. The VT16 includes 24 nozzles for bubbling bath and 8 nozzles for whirlpool; the VTH16 includes 20 nozzles for bubbling bath and 5 nozzles for whirlpool.

The water loading and unloading system can be manual, automatic or combined. In automatic configurations, filling and emptying are managed by electronics by means of solenoid valves and timers; for active functions, the configurable duration of the treatments is between 10 and 25 minutes in increments of 5 minutes. For compressed air versions, the configuration can include a turbine, blower or centralized compressed air. These details are important because they directly link the operating principle to the repeatability of performance and the definition of safety checks.

On the scientific level, the bath is located in the wider field of balneotherapy and thermal hydrotherapy, in which the potential therapeutic effect is linked to the combination of mechanical, thermal and chemical stimuli. The general literature on balneotherapy describes the role of immersion, hydrostatic pressure, temperature and mineral composition of water as factors that can influence circulation, musculoskeletal symptoms, dermatological conditions and perceived well-being [31]. In this framework, clinical studies on different indications, such as psoriasis, chronic venous insufficiency and lymphedema of the lower limbs, show that thermal or hydrotherapy treatments can be associated with improvements in clinical or symptomatological parameters, although with limitations related to the specificity of protocols and the non-immediate transferability of results.

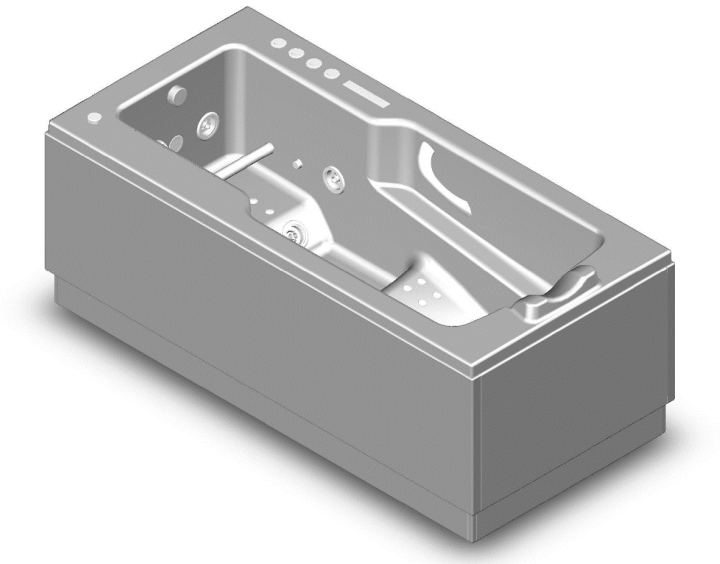


Figure 5.1: Overall view of the VT16 hydrotherapy tub.

a single device [32, 33, 34]. For VT16/VTH16, these sources do not constitute direct evidence of product efficacy, but help to explain which parameters should be documented: temperature, duration, hydromassage mode, possible ozonation, water hygiene, expected population and limits of use.

The indications given in the company documentation include heterogeneous therapeutic areas, including rheumatic diseases, dermatological diseases not in active phase and with intact skin, vascular and lymphatic, osteoarticular and musculoskeletal, neurological, uro-gynecological and aesthetic medicine applications. From the MDR point of view, this amplitude requires special caution: each indication must be consistent with treatment, expected population, contraindications, clinical evidence and information provided to the user.

Among the most important technical elements are the pump, the air/water circuit, the use of the Venturi effect, the ozone generator, electronic controls, level and temperature sensors, the timer, automatic discharge and disinfection. Each of these elements contributes to the definition of device performance and, at the same time, introduces specific risk profiles that need to be addressed in the technical documentation. Consider, for example, the risks related to the presence of water in combination with electrical components, the need to correctly define the operating limits of the circuit, the surveillance of the patient in immersion, the compatibility of ozone with the environment and the user, or even the management of sanitation.

The device is particularly useful in the thesis work because it allows to observe how MDR compliance must also be built in relation to electromechanical components, electromagnetic compatibility, operational safety parameters and correlation between essential performance and risk. In this sense, the VT16/VTH16 is the ideal complement to the IMT19: the two devices show in fact two different variations of the regulatory problem within the same

company context.

5.2 Documentation requirements under the MDR

The analysis of the technical description of the VT16/VTH16 shows that, for a professional spa hydrotherapy tub, the technical file must document not only the presence of a tank and its controls, but the entire relationship between treatment, water/air circuit, electrical system, installation configuration and patient profile. Unlike the IMT19, in which performance is mainly linked to the generation and controlled delivery of aerosols, gases or local jets, in the VT16/VTH16 the performance depends on the immersion of the patient, the transfer of thermal and mechanical energy and the safe management of large volumes of water.

From the point of view of Annex II, the description of the device must therefore clearly distinguish the two variants VT16 and VTH16, indicating size, capacity of the tank, number of nozzles and nozzles, hydromassage system, gurgled bath system, possible ozone generator, chromotherapy, operator panel, sensors, electric pump, turbine or blower, automatic discharge and disinfection system. The VTH16 also requires a specific description of the side door, the internal handle and ergonomic solutions for elderly, disabled or reduced mobility patients.

The intended purpose must be formulated in such a way as to link each treatment to its performance: simple bath, water whirlpool, bubbling bath, air/water hydromassage with ozone and chromotherapy. In particular, therapeutic indications associated with rheumatic, dermatological, vascular and lymphatic diseases, osteoarticular, musculoskeletal, neurological or uro-gynecological diseases must be reported in a consistent manner between technical description, user manual, clinical evaluation and risk analysis. If a clinical condition is indicated only in part of the dossier, or if it is not supported by a proportionate clinical rationale, it can generate regulatory criticality.

Another point concerns the identification of the user and the intended population. The documentation must specify that the device is intended for spa establishments and must be used by trained professional personnel. For frail, elderly, disabled, children or pregnant women, treatment should be subject to supervision and medical authorisation, as provided for in the use information. These elements are not simple operational recommendations, but risk control measures that must be consistent with IFU, operator training and benefit-risk assessment.

The risk analysis of the VT16/VTH16 should also consider specific scenarios: electrical risk in a humid environment, thermal risk related to water temperature, mechanical risk of jets, risk of falling or difficulty of entry and exit, microbiological risk of the circuit, risk related to ozone, incorrect use of controls, failure to discharge or improper load, failure to disinfect and use in the presence of contraindications. This is why important controls such as level and temperature sensors, timers, loading/unloading solenoid valves, disinfection procedures, scheduled maintenance, verification of surface integrity and clear instructions for the operator.

In summary, part VT16/VTH16 confirms that the MDR documentation must translate the technical complexity of the device into a coherent system of information: product description, variants, performance, indications, usage limits, contraindications, safety checks, clinical evidence and post-market activities. The bath should therefore not be treated as a simple thermal furniture, but as an active electromedical device whose performance depends on the correct integration between design, installation, professional use and life cycle management.

5.3 Technical architecture and operating principle

The company's technical documentation allows to describe in greater detail the functional logic of the VT16/VTH16.The tank is not made up of a single subsystem, but integrates hydraulic circuit, pneumatic circuit, electromechanical actuators, sensors and control logic. The treatment therefore depends on the coordination between tank filling, availability of water, activation of the pump or air source, eventual generation of ozone, timing and subsequent discharge. This architecture is relevant for MDR purposes because each subsystem introduces specific performance requirements and, at the same time, risk control measures.

For the water whirlpool, the documentation describes an internal electric pump that draws water from the tank through the suction nozzle and recirculates it to the dispensing nozzles. Inside the venturi effect allows the mixing between water and air, generating the massage jet. On the VT16 there are eight whirlpool nozzles and four air regulators placed on the edge of the tank, used to modulate the air component dragged into the jet. The ability to orient the nozzles allows to distribute the action in different areas of the body, but it requires that flow, perceived pressure and orientation remain compatible with the intended purpose. The gurgled bath instead uses a separate pneumatic circuit. The air is supplied, depending on the configuration, by a turbine, blower or by a centralized compressed air network and is distributed through nozzles placed at the bottom of the tank. The VT16 is documented with 24 nozzles, while the VTH16 uses 20 nozzles. The difference between water hydromassage and gurgled bath is therefore structural: in the first case the dominant element is hydraulic recirculation by pump, in the second the introduction of air into the volume of water.

The overall performance of the tank derives from the interaction between three distinct functional pathways: water management, hydromassage recirculation and the pneumatic circuit of the bubbling bath. The electronic control supervises sensors, actuators and timings common to the different paths. As a result, a change to a pump, sensor, control software, exhaust system or pneumatic configuration can affect both performance and risk management.

Electronic control, sensors and functional interlocks

The automatic operation is managed by an electronic board connected to the operator panel placed on the edge of the tank. The technical documentation describes six main commands: whirlpool, bubbling bath, ozone/disinfection, automatic loading, automatic discharge and chromotherapy. The display shows the water temperature, the residual treatment time and the indication of no water. This interface is a safety element as well as a control element, because it makes available to the operator information necessary to check the status of the tank before and during therapy.

A level sensor verifies the presence of water at an altitude above the hydromassage nozzles. According to the design documentation, in the absence of a level the therapeutic functions are kept disabled, with the exception of chromotherapy. This logic avoids the activation of some actuators in conditions that are not compatible with their normal operation and must therefore be considered both in software/functional verification and in risk analysis. An additional sensor controls the level of the disinfectant tank in configurations involving automatic disinfection.

The water temperature is measured by a sensor installed on the section affected by the suction of the electric pump and remains available even when the hydromassage program is not active. From the point of view of verification, this makes it necessary to distinguish only the display of the parameter from the ability of the system to prevent inappropriate thermal conditions: any limits or alarms must be traced back to the design specification and the instructions for use, without giving the sensor any undocumented functions.

The loading and unloading system can be manual, automatic or combined. In automatic configurations the electronics control the solenoid valves, while in manual configurations the taps prepared for installation. The documentation describes two possible logics for automatic unloading: a mode in which the unloading is controlled by the operator at the end of the therapy and a mode in which the opening occurs automatically after a short delay. There is also a logic that closes the drain when, during emptying and in the presence of a level, a function such as hydromassage is activated. These sequences make clear the need to verify not only the individual actuator, but also the transitions between operating states.

For active functions, business documentation indicates configurable durations of between 10 and 25 minutes in increments of 5 minutes; the timer associated with the download can be configured separately. These intervals should be considered as device configuration specifications and not as universal clinical parameters: the actual duration of treatment remains linked to the prescription or indications of the operator in the intended purpose.

5.4 Differences between VT16 and VTH16 and usability implications

VT16 and VTH16 share the same general functional logic, but differ in geometry, accessibility and expected population. The VT16 is a traditional tank with a fiberglass-reinforced ABS/PMMA body; the documentation shows a total size of about 1815 x 865 x 680 mm and a volume of 270 liters without a patient. The VTH16 uses a structure with a stainless steel frame and a fiberglass shell covered with gelcoat, with documented dimensions of about 1500 x 714 x 1030 mm and the same nominal volume of 270 liters.

The most significant difference is access. The VTH16 is intended in particular for elderly, disabled or people with reduced mobility who are able to maintain the sitting position independently. To facilitate entry and exit, it is equipped with a side door, with opening reported by the documentation of about 160 degrees, and an internal handle for positioning the patient. This configuration modifies the usability profile and requires consideration of specific risks related to patient handling, correct door closure, treatment stability and operator surveillance.

Table 5.2: Technical-functional comparison between VT16 and VTH16 based on company documentation.

Characteristic	VT16	VTH16
General configuration	Traditional tub for immersion treatments.	Bathtub designed to facilitate access for people with reduced mobility.
Tub body material	ABS/PMMA co-extruded with fiberglass reinforcement.	Fiberglass coated in gelcoat on stainless steel frame.
Patient access	Entrance from the top with handles and support bar.	Side door and internal handle; specific verification of the closure and safe use is required.
Air bubble bath	24 nozzles.	20 nozzles.
Hydromassage	8 jets.	5 jets.
Characteristic patient population	General population within the limits of use, with surveillance for fragile subjects.	Older adults, people with disabilities or motor difficulties who can sit independently.
Documented maximum load	150 kg.	150 kg.

From the MDR point of view, the presence of the side door should not be treated as a simple aesthetic difference. It introduces a safety-relevant mechanical function: opening and closing conditions, sealing integrity, operator use, maintenance and behaviour in the event of foreseeable error must be defined. Similarly, the handle and internal geometry must be assessed against the expected population and the patient's ability to enter, take the correct position and exit safely.

5.5 Technical and performance verification to be planned

The architecture described allows you to transform the tank subsystems into verification objects. The verification should not be limited to the demonstration that the function "activates", but should define test conditions, configuration, observed measurement and acceptance criteria. For example, the level sensor verification must demonstrate both the correct water detection and the behavior of the functions that depend on this information; similarly, the discharge verification must consider the different configurable modes and transitions during the operating cycle.

Table 5.3: Examples of verification areas for VT16/VTH16 to be linked to specifications and risk management.

Subsystem	Planned verification and supporting evidence
Hydraulic circuit	Verification: recirculation, sealing, flow rate and distribution to the nozzles. Criterion: no leakage; pump working; repeatable cycle according to specification. Evidence: V&V protocol and report.
Pneumatic circuit	Verification: air source, circuit continuity and nozzle distribution. Criterion: Consistency with authorised configuration and conditions of use. Evidence: functional report.
Sensors	Verification: water level and temperature. Criterion: accuracy and repeatability according to specification; correct interlock response. Evidence: test report and software traceability.
Filling / draining	Verification: operating sequences in manual, automatic or combined modes. Criterion: correct closure, status transitions and abnormal condition management. Evidence: functional report.
Structure and access	Verification: patient load, supports and, for VTH16, side door, handle and input/output sequence. Criterion: mechanical integrity and safe execution of the operations envisaged. Evidence: structural and usability report.
Disinfection	Verification: effectiveness and repeatability of the cycle in the relevant configurations. Criterion: Effectiveness under the worst foreseeable conditions and consistency with operating instructions. Evidence: protocol and validation report.

The tests should be selected from the final specifications of the device and from the risk assessment. The table therefore has a planning value and does not imply that all tests are necessary for each variant. An ozone-free model, for example, does not require the characterization of ozone production; a variant with manual load requires a different attention to the information provided to the installer and operator.

Electric safety deserves a separate treatment because the tank operates in a humid environment and integrates electrically powered components. The test reports available in the dossier constitute evidence to be reviewed with respect to the current configuration and the state of the art of regulation. The same logic applies to EMC, usability and biological evaluation of the parts in contact with the patient.

Ozone, disinfection and test conditions

In the relevant configurations, ozone is generated by a dedicated module and conveyed into the air/water circuit. The company technical documentation describes a generator based on corona discharge and reports, for the component concerned, an indicative production of about 90 mg/h at a flow of about 150 L/h. These data are specific to the project component/documentation and should not be transformed directly into an exposure safety statement. Regulatory verification must establish how much of the ozone is actually transferred to water, what fraction can reach the environment and what limits are applicable in real conditions of installation and ventilation.

Consequently, the V&V plan should distinguish at least the generator performance, the circuit distribution, the concentration or exposure in the environment and the behaviour in abnormal conditions. Any acceptance criterion must be derived from the applicable specifications and risk management, not from a value assumed arbitrarily. This is a particularly clear example of how a technical feature of the component should be transformed into a system evidence.

Automatic disinfection is a second critical process. Its effectiveness cannot be demonstrated by the activation of the program alone: it is necessary to define concentration of the product used, volume and points of the circuit reached, contact time, rinsing, worse configuration and microbiological or chemical verification method. In this case, the validation must be linked to the risk that the process intends to control and to the operating instructions that the user must follow.

Finally, usability and mechanical performance must be considered together for the VTH16. Lateral access may reduce entry difficulties for certain categories of patients, but it introduces additional operational activities for staff. A structured assessment should therefore observe a sequence of opening, transfer, positioning, closing, treatment and exit, including reasonably foreseeable misuse scenarios. Verification of the interface and procedure is particularly important because the intended population includes people with reduced mobility. These considerations make it possible to directly link the technical description of the tank to the planning of the evidence: each relevant subsystem is traced back to a requirement, a risk and an expected documentary output.

5.6 Documentation implications of the tub architecture

The technical analysis shows that the VT16/VTH16 file must maintain a precise correspondence between the marketed variant and the actual installed configuration. The company documentation includes variants with differences in the availability of hydromassage, gurgled bath, ozone, chromotherapy, automatic disinfection and loading/unloading modes. Consequently, the designation “VT16” or “VTH16” alone is not sufficient to identify all the characteristics that affect compliance: the configuration must be able to be reconstructed through product code, base list, labelling and installation documents.

For risk management, this modularity implies that the applicability of a hazard or control measure may depend on the set-up. The risk associated with ozone must be treated in variants incorporating this function; the risk linked to the side door is specific to the VTH16; the exhaust logics must reflect the manual or automatic mode actually installed. The traceability matrix should therefore include the reference to the configuration to which each requirement and each test apply.

Instructions for use must also be consistent with this approach. The operator must be able to distinguish the available functions, the conditions necessary for activation, limitations, maintenance and cleaning/disinfection procedures. Where risk control depends on patient surveillance, temperature verification or a specific input/output sequence, this information shall be expressed in a clear and verifiable manner in the UFIs and in the possible formation of the user.

From the evidence point of view, the most robust criterion is to associate each configuration with a minimum set of type tests and production controls. The type tests demonstrate the conformity of the design and main performance; the production controls confirm instead that the manufactured unit corresponds to the approved configuration and functions properly before delivery. Where a change affects a critical component, change control shall determine whether a documentary review is sufficient or whether the previous verifications need to be repeated in full or in part.

The expansion of the VT16/VTH16 part allows the rebalancing of the case study compared to the IMT19.The two devices share the need to integrate electronics, fluids, electrical safety, usability and hygiene, but have different criticalities: the IMT19 is characterized by the modularity of the care places and the plurality of the therapies provided; the VT16/VTH16 from the presence of the patient immersed, the humid environment, the structural loads and the interaction between the water / air circuit and the accessibility of the tank. This difference justifies distinct V&V plans even within the same regulatory method.

Chapter 6

Operational pathway for achieving and maintaining MDR compliance

The previous chapters described the document review carried out on IMT19 and VT16/VTH16 devices and the main elements of the technical dossier required by Regulation (EU) 2017/745. To make the work more effective, it is useful to translate these requirements into an operational path that allows you to plan activities, identify missing evidence and maintain consistency between device, technical documentation and quality system over time. The proposed path does not replace business procedures, but provides a reusable structure to organize the MDR adaptation of the analyzed devices.

6.1 Project setup and gap analysis

The project setting should start from the regulatory identity of the device and proceed to the definition of the actions necessary to close the identified gaps. A concrete operational sequence can be articulated in the following steps:

1. identification of the device, models, variants and configurations;
2. definition of the intended purpose and associated claims;
3. identification of intended users, patient population, indications and contraindications;
4. classification of the device and choice of conformity assessment procedure;
5. identification of technical standards, common specifications and other applicable references;
6. census of available documents and their version;
7. execution of the gap analysis with respect to the applicable requirements;
8. allocation of managers, priorities, deadlines and criteria for closure of actions.

The gap analysis should therefore not be limited to verifying the presence or absence of a document. For each requirement, it is necessary to establish whether the available evidence is up-to-date, consistent with the current configuration of the device and linked to the other sections of the dossier. Table 6.1 shows an example of the operating log. The reported status is illustrative and must be confirmed on the company documentation actually available.

Table 6.1: Example of operational register for gap analysis.

Activity	Operational data
Verification of intended purpose	Input: user manual and technical data sheet. Responsible party: Regulatory / R&D. Output: approved intended purpose. Status: to be updated.
Classification	Input: intended purpose. Responsible party: Regulatory. Output: classification rationale. Status: available.
Gap analysis	Input: Annexes I–III and company documents. Responsible party: QA / Regulatory. Output: action plan. Status: to be completed.

Article 10 of the MDR requires the manufacturer to supervise risk management, clinical evaluation, technical documentation, quality management system, UDI, post-market surveillance and corrective and preventive actions in a coordinated manner. These elements are therefore more effective if represented as part of a single business process, rather than as independent obligations [1]. In this setting, gap analysis becomes the link between regulatory requirements, document status and project plan.

6.2 Evidence and test planning

The experimental part of compliance should be set through a verification and validation plan defined prior to the execution of the tests. The plan should not anticipate unavailable results, but specify for each activity what needs to be demonstrated, by what method and what evidence should be produced. The minimum structure is shown in Table 6.2.

Table 6.2: Minimum fields of the verification and validation plan.

Field	Content to define before execution
Requirement or risk	Applicable requirement, GSPR, specification or risk justifying verification.
Measured characteristic	Quantity, function or performance to be verified.
Test method	Standard, internal procedure, protocol or validated method.
Sample / configuration	Model, variant, accessory, software version and representative conditions.
Laboratory / responsible party	Internal function or external laboratory in charge.
Acceptance criterion	Criterion defined a priori on the basis of requirement, risk, specification or claim.
Document produced	Protocol, raw data, reports or other controlled record.
Status	Planned, available, to be updated or not applicable, with the corresponding rationale.

The acceptance criterion shall be set before the test and be linked to a requirement applicable, a technical standard, a design specification, a risk control measure or a declared performance. In this way the test report does not remain an isolated document, but constitutes traceable evidence against the requirement that motivated the verification.

For IMT19, the plan should consider at least electrical safety and electromagnetic compatibility; verification of flow, pressure, temperature and duration of treatments; repeatability of delivery; characterisation of aerosol, where applicable; efficacy of the sanitisation cycle; biocompatibility of accessories in contact with the patient, to be framed according to the ISO 10993 series [36]; verification of software, consistent with the life cycle required by IEC 62304 [37], usability and cybersecurity aspects; and finally compatibility between module, therapy, accessory and authorised configuration. Where a test is entrusted to an external laboratory, the choice should take into account the competence for the specific method and the applicable accreditation according to ISO/IEC 17025 [35]. These activities are consistent with the technical and risk profiles already described for the device and must be selected according to the configuration actually evaluated.

For VT16/VTH16, planning should consider electrical safety in a wet environment; accuracy and reliability of level and temperature sensors; operation of pump, blower, timer, solenoid valves and discharge; flow and distribution of jets; structural strength and maximum load; safety of the side door of VTH16; effectiveness of disinfection; production and exposure to ozone in relevant configurations; usability for patients with reduced mobility. Again, this is not a list automatically applicable to each variant, but a set of candidate verifications to be confirmed by means of intended purpose, GSPR, risk analysis and product architecture.

The actual applicability of each test therefore derives from its intended purpose, declared performance, risk analysis, general safety and performance requirements and device configuration. Annex II requires that the technical documentation identify the applicable requirements and the methods used to demonstrate their conformity, including the link to the relevant documentary evidence [1]. This setting makes it possible to build an array in which each test has an explicit rationale and verifiable output.

Distinction between activities carried out and planned activities. In this work, the review carried out during the internship mainly concerns the document analysis and the definition of the path necessary to complete the demonstration of conformity. The tests mentioned in the verification and validation plan are then treated as tasks to be planned: for each the requirement or risk to be verified, the test configuration, the method, the acceptance criterion and the document to be produced are defined.

This setting should be distinguished from existing business evidence, such as reports or controls previously performed on the legacy device. These documents can be used as input to the review and must be reviewed in relation to the applicable configuration and state of the art, but do not represent experimental activities performed within the the thesis. The execution of the new tests, the collection of the results and the approval of the related reports are therefore subsequent activities, to be carried out on the final configuration of the device according to the procedures of the quality system.

6.3 Development and review of the technical file

Once the gaps are defined and the evidence is planned, the technical file should be constructed as a system of linked documents. The flow proposed in Figure 6.1 starts from device

identification and ends with compliance maintenance, providing review and feedback points when changes, non-compliances or new post-market data emerge.

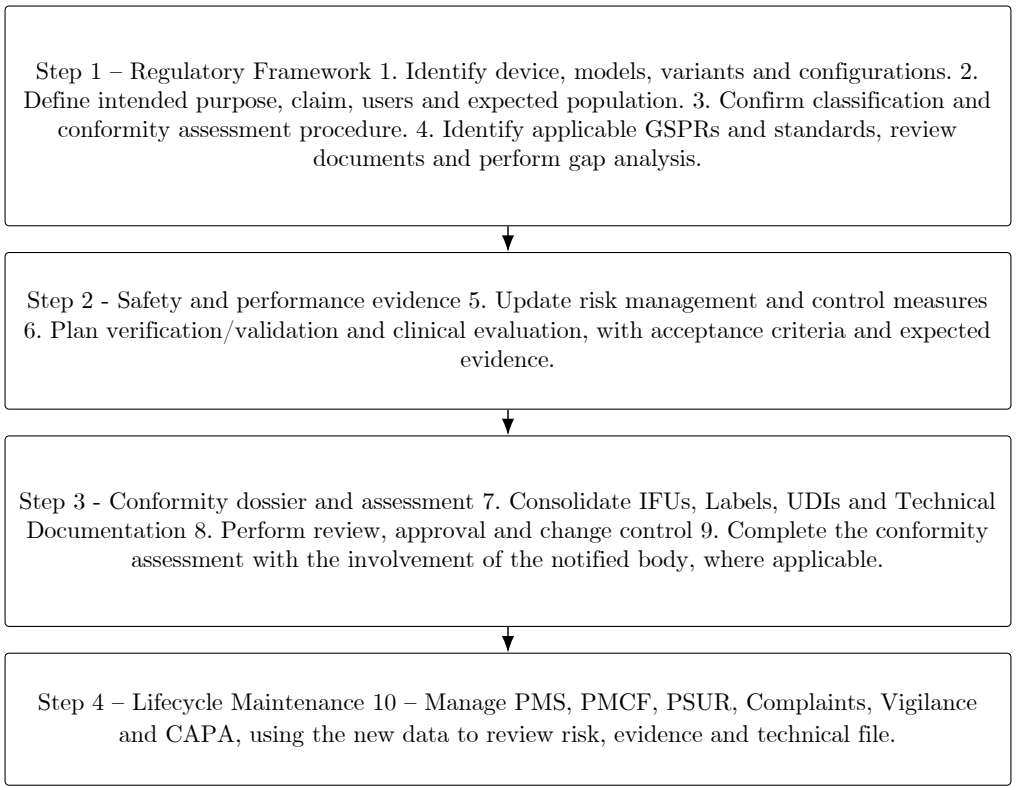


Figure 6.1: Proposed operating flow for construction, review and maintenance of the technical file.

The central element of the flow is traceability. Any applicable requirement should be able to be followed up to the associated risk, the control measure, the verification carried out and the evidence stored. Table 6.3 shows a minimum matrix structure, to be filled with device-specific references.

Table 6.3: Structure of the traceability matrix requirement–risk–evidence.

Element to be tracked	**Content to be recorded**
Requirement	GSPR, regulatory requirement or applicable specification.
Risk	Hazard, sequence of events and associated hazardous situation.
Control measure	Design, procedural or information measure adopted.
Verification	Method or test used to verify the control measure or performance.
Evidence	Result, test report or other available objective evidence.
Document	Unique reference to the file, version and section of the technical file.

The traceability matrix represents the level of detail; at the system level, the same links can be read through the document map shown in Figure 6.2. The figure does

not represent a timeline, but the main areas that must remain mutually consistent within the technical file.

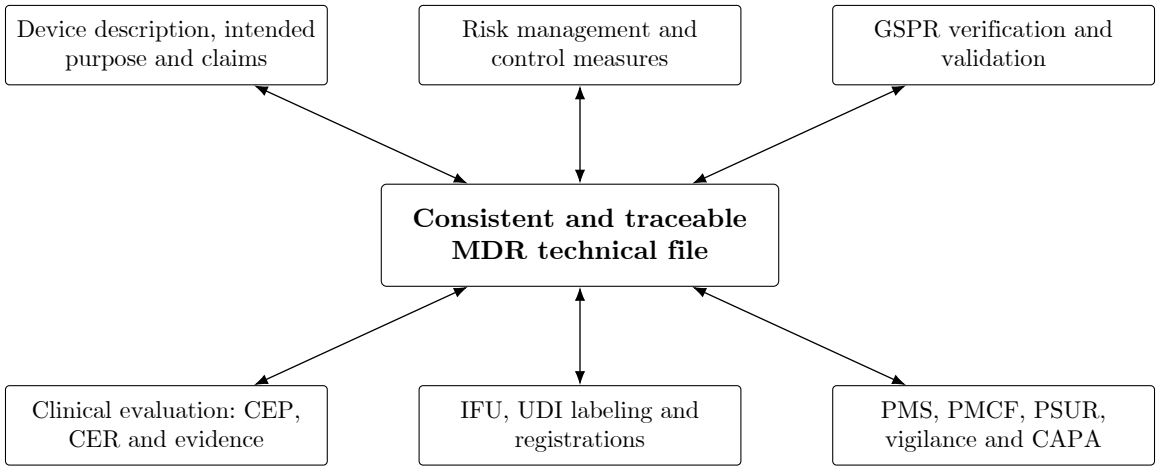


Figure 6.2: Map of the main document areas that contribute to the consistency of the technical file.

In order for the matrix to remain reliable over time, the dossier must be supported by a consistent documentary check. Version control must make identifiable current document, author, reviewer, approver and motivation of the change; change control must assess the impact of the change on risk, performance, clinical evaluation, V&V, labelling and registrations; supplier qualification and monitoring must be proportionate to the criticality of components and services. Non-compliance and CAPA must be linked to the evidence that led to its opening and to the verification of the effectiveness of the actions taken.

Document review also requires defined roles. Regulatory coordinates the interpretation of requirements and compliance strategy; QA oversees the quality system, document control, CAPA and suppliers; R&D maintains technical responsibility for specifications, configurations and modifications; Clinical manages clinical evaluation and connection with PMCF; production and laboratory provide process and test evidence; PRRC carries out the responsibilities provided for in Article 15; the notified body takes part in the conformity assessment activities envisaged for the chosen class and procedure [1]. For Class IIa devices, Article 52 provides for the involvement of a notified body in accordance with the applicable procedures of Annexes IX or XI [1].

6.4 Maintaining compliance

The CE marking does not conclude the regulatory process. After placing on the market, the manufacturer shall maintain an active system capable of collecting and evaluating data, detecting signals and updating documentation when necessary. The proposed path includes PMS and PMCF, drafting and updating of the PSUR, complaint handling, trend reporting, vigilance, CAPA, updating of the CER and risk management, change control, periodic review of the applicable rules and updating of labels, UDIs and registrations.

For Class IIa devices, the PSUR shall be updated as necessary and at least every two years; the report shall summarise, among other elements, the conclusions of the benefit-risk balance, the main findings of the PMCF and the exposure data of the device on the market [1]. Its content should not be treated as a separate report from the dossier, but as a source that may

lead to new actions, revisions of risk management or changes to the information provided to the user.

PMCF is a continuous process that updates the clinical evaluation and should be considered in the PMS plan. The results of PMCF activities should be analysed and used, where necessary, to update clinical evaluation, risk management documentation and surveillance planning [1]. The same logic applies to complaints, accidents, non-compliances and user feedback: each post-market data must be traced back to the device and configuration concerned, assessed against the risks already known and transformed into a documented action when a new need for control emerges.

In this perspective, the application contribution of the thesis consists in the design of a verifiable and reusable adjustment process. The gap analysis, the verification and validation plan and the traceability matrix described in the chapter allow the MDR requirements to be translated into assignable tasks, expected evidence and closure criteria, while keeping the test planning separate from the actual available experimental results.

6.5 Overview of application to the devices analysed

The usefulness of the proposed method emerges when the same phases are traced back to the two devices examined in the thesis. IMT19 and VT16/VTH16 share the need to demonstrate safety, performance, document consistency and lifecycle control, but have different technical profiles. Table 6.4 summarises the main areas to be monitored without giving the activities an unverified experimental state.

Table 6.4: Synthetic application of the operating path to IMT19 and VT16/VTH16.

Aspect	**IMT19**	**VT16/VTH16**
Main verification areas	Controlled delivery; pressure, flow rate, temperature and duration; aerosol where applicable; sanitization; software and accessories.	Water/air circuit; temperature and level; jets and recirculation; structure and load; disinfection; ozone in relevant configurations.
Characterising risk profiles	Pressure and temperature; aerosolization; contact with mucous membranes; configuration errors; hygiene of circuits and accessories.	Wet environment; water temperature; patient inlet and outlet; mechanical risk; circuit microbiology; ozone exposure.
Evidence to be planned	Performance V&V; electrical safety and EMC; biological evaluation of accessories; sanitization validation; software verification.	Functional V&V; electrical safety; structural checks; jet distribution; disinfection validation; ozone characterization.
Expected documentation outputs	Test report; risk management and GSPR update; IFU/label alignment; clinical and post-market documentation update.	Test report; risk management and GSPR update; IFU alignment and configurations; update of clinical and post-market documentation.
Status in this study	Methodologically planned activities; execution and results to be confirmed on the final configuration and business documentation.	Methodologically planned activities; execution and results to be confirmed on the final configuration and business documentation.

The comparison shows that the value of the route does not lie in the application of a fixed list of tests, but in the ability to start from the identity of the device and to build a coherent document chain between requirements, risks, evidence and post-market activities. For the IMT19

the focus is mainly on the correct delivery of therapies, modular configurations and accessories; for the VT16/VTH16 the integration between humid environment, hydraulic circuit, tank structure and user safety is more important. In both cases, the closure of the gaps shall be documented and reviewed before the demonstration of conformity is considered complete.

6.6 Verification and validation matrix for IMT19

The company documentation of the IMT19 makes it possible to make the V&V model more concrete without assigning tests not performed to the internship. In particular, the design and manufacturing documentation already describes end-of-line controls related to hydraulic tightness, the implementations of the Master board and the treatment stations, the correspondence between the programmed version and enabled therapies, the functionality of care, electrical safety and dielectric rigidity. These activities are a useful starting point, but in the MDR path they must be reviewed with respect to the final configuration, the state of the art normative and the new treatments that may be introduced.

Table 6.5: Example of V&V matrix applied to IMT19 based on available technical documentation.

Area / risk	Verification plan
Fluid circuit integrity	Feature: sealing of pipes, joints and additions. Method/criterion: hydraulic leakage test; no leakage under defined conditions, with pressure and duration consistent with the final specification. Evidence: protocol and sealing report.
Treatment station configuration	Feature: enabled therapies and software/configuration version. Method / criterion: comparison between project and programmed version; correspondence between authorized configuration, accessories, software and IFU. Evidence: configuration record and functional report.
Delivery performance	Feature: suction, nebulisation, gurgling or flow. Method / criterion: functional testing for therapy; quantitative parameters defined a priori when necessary to support the claim. Evidence: Performance report for therapy.
Electrical risk	Feature: Earth continuity, leakage currents and insulation. Method/criterion: electrical safety and dielectric rigidity according to the limits applicable to the final configuration. Evidence: Electric safety report.
Microbiological risk	Feature: effectiveness of steam sanitization. Method / criterion: automatic cycle with temperature monitoring; time-temperature profile and microbiological reduction to be validated under the worst conditions expected. Evidence: protocol and validation report.

The matrix highlights an important distinction. Some legacy controls can be maintained as production controls or historical evidence, but the MDR V&V must demonstrate that the method is still adequate to support the current specification. For example, visual nebulisation control can be useful in routine testing, while demonstration of a declared aerosol performance may require dedicated quantitative characterisation. Similarly, temperature monitoring during sanitation documents the cycle, but microbiological efficacy must be supported by risk-proportioned validation.

6.7 Verification and validation matrix for VT16/VTH16

For the thermal bath, the planning of the verifications must reflect the installed configuration. The technical documentation describes an architecture with electric pump for hydromassage, turbine/blower or centralized air for the bubbling bath, level and temperature sensors, manual or automatic loading and unloading, possible ozone generator and, in the relevant configurations, automatic disinfection. The VTH16 also introduces the side door and an internal handle designed to facilitate access for users with reduced mobility.

Table 6.6: Example of V&V matrix applied to VT16/VTH16.

Area / risk	Verification plan
Presence of water	Feature: level detection and blocking of dependent functions. Method/criterion: Tests at controlled levels, including empty-fill-operational level transitions; threshold, hysteresis and safe behavior consistent with specification and risk management. Evidence: sensor / interlock report.
Hydromassage performance	Feature: recirculation, casting and distribution. Method / criterion: flow/pressure, or equivalent parameters, in representative points; uniformity and repeatability consistent with specifications and claims. Evidence: Performance report.
Air bubble bath	Feature: air delivery and bubble distribution. Method / criterion: verification of the pneumatic source and the dispensing points; consistency with configuration, intended purpose and safety limits. Evidence: functional report.
Thermal risk	Feature: measurement of water temperature. Method/criterion: comparison with sample instrument in multiple conditions; accuracy, repeatability and out-of-range management according to specification. Evidence: sensor verification report.
Accessibility VTH16	Feature: door, handle and input/output sequence. Method/criterion: mechanical testing and usability assessment with representative scenarios; integrity and safe completion of critical tasks. Evidence: structural and usability report.

Dedicated protocols are needed for ozone and disinfection. The nominal generator data or the activation of the cycle are not, alone, sufficient to demonstrate the conformity of the system. The plan shall define reasonably foreseeable installation conditions, configuration, measurement points and worst-case scenarios, linking the results to the risk assessment and information provided to the user.

6.8 Priority criteria for closing gaps

Once the gap analysis is populated, project management requires a priority of intervention. Priority should not depend solely on the ease with which a document can be updated, but on the impact that the gap has on the ability to demonstrate compliance. For the case study, it is useful to adopt three main criteria: relevance for safety and performance, dependence on other activities and relevance for conformity assessment.

Table 6.7: Proposed criteria for prioritising adaptation actions.

Criterion	High priority when	Example in the case study
Safety / performance	The gap may compromise a control measure, essential performance or acceptability of risk.	Validation of cleaning and disinfection, electrical safety, delivery pressure, the VTH16 door and ozone exposure.
Dependency	The gap prevents subsequent tests or documents from being properly defined.	Intended purpose not finalised, configurations/accessories not defined, incomplete performance specifications.
Conformity assessment	Evidence is required for GSPR, technical documentation or review of the notified body.	Classification rationale, V&V, CER, GSPR, PMS/PMCF and change traceability.

Priority can be qualitatively represented as high, medium or low, provided that the rule is defined before allocation and applied consistently. A more complex numerical classification would only make sense if the company had formalized criteria and sufficient data; in this work it is preferable not to introduce arbitrary scores.

A second element is temporal dependence. The definition of the intended purpose and the configuration must precede the finalization of the risk management and the V&V plan; in the same way, a design change not yet stabilized makes it premature to carry out tests that may need to be repeated. Planning should therefore identify not only the final deadline, but also the relationships between activities and the elements that are prerequisite for starting the next steps.

Finally, the closure of a gap must include the verification of the effectiveness of the action. If the gap is documentary, the review shall confirm that the information has been aligned in the related documents; if the gap requires proof, the closure shall take place only after approval of the report and management of any deviations; if the gap is resolved by a justification of non-applicability, it shall be technically justified and approved.

6.9 Proposed sequence for implementing the plan

The practical application of the route can be organized into four work blocks. The first block stabilizes the regulatory identity of the device: configurations, intended purpose, indications, population, classification and compliance procedure. The second consolidates the documents that act as input to the tests, in particular specifications, risk management and GSPR. The third party performs or updates the verification and validation activities and integrates the results into the technical documentation. The fourth prepares compliance maintenance through PMS, PMCF, PSUR, change control and periodic reviews. For IMT19, the sequence should prioritise the final definition of new therapies and related accessories, because these elements influence risk management, performance to be verified, biocompatibility, software/IFU and clinical evaluation. The test checks already present in the documentation can be used as a basis for distinguishing what belongs to the production control from what must be demonstrated by means of type tests or dedicated validations.

For the VT16/VTH16 the first step is the reconstruction of the configuration by variant: loading/unloading mode, presence of hydromassage, gurgled bath, ozone, chromotherapy and disinfection. From this map comes the applicability of the checks. The VTH16 also requires a specific path for door, access and usability with a population with reduced mobility, while ozone variants require characterization of function and exposure under the intended installation conditions.

The final result of the project should be a closing dossier in which each action of the gap analysis is associated with an approved output. The dossier is not a new mandatory regulatory document, but an internal tool to demonstrate that the planned activities have been completed and that the updates have been incorporated into the relevant documents. In this way the path proposed in the thesis becomes verifiable: an auditor can start from the initial gap, follow the assigned action, identify the evidence produced and verify where it has been integrated in the technical file.

This structure also allows to keep distinct the design part developed in the thesis from future business activities. The work carried out defines the method, priorities, matrices and expected outputs; the execution of the tests, the approval of the reports and the formal closure of the actions remain activities to be carried out on the final configuration of the devices and according to the procedures of the quality system.

Chapter 7

Conclusions and future developments

This thesis analyzed the adaptation to Regulation (EU) 2017/745 through an industrial case study on existing spa medical devices. The work was not set as a new product design, but as a critical review of the technical documentation and links needed to support MDR compliance. This perspective has made it possible to observe that, for established devices, the main difficulty does not necessarily lie in the availability of individual documents, but in their completeness, in their updating and above all in the mutual consistency between intended purpose, declared performance, risk management, technical and clinical evidence, information provided to the user and post-market activities.

The analysis of the IMT19 showed the regulatory relevance of the modularity of the device. The presence of different treatments, accessories and delivery carriers requires that each configuration is explicitly traced back to its intended purpose, technical parameters, risks and evidence available. The review covered in particular the description of the device, terminology, intended purpose, distinction between accessories and components, classification, information provided by the manufacturer, GSPRs, risk management setting and verification and validation activities to be planned. The introduction of endotympanic insufflation and gingival irrigation also showed that the extension of the intended purpose cannot be treated as a simple nominal update, because it simultaneously involves dispensing parameters, risks, instructions for use, clinical evaluation and post-market planning.

For the VT16/VTH16, the work highlighted a different set of critical issues. The performance of the device depends on the integration between water/air circuit, electromechanical components, temperature, jets, loading and unloading systems, disinfection and, in the relevant configurations, generation of ozone. Added to these are the ergonomic and accessibility aspects of VTH16 for elderly, disabled or reduced mobility patients. Again, compliance cannot be supported by a generic description of the tank, but requires a sufficiently detailed technical representation to link configuration, treatment, expected population, risks and control measures.

A central result of the work was therefore the transition from a predominantly documentary reading to an operational proposal. Chapter 6 translates the regulatory requirements into a sequence applicable to the adaptation project: identification of the device and the intended purpose, classification, document census, gap analysis, evidence planning, traceability construction, review of the dossier and maintenance of life-cycle compliance. The requirement–risk–control–check–evidence matrix makes it possible to make explicit the link between what the regulation requires and the document supporting its demonstration. Similarly, the verification and validation plan allows you to define before testing the requirement to be verified,

the configuration, the method, the responsible, the acceptance criterion and the expected document output.

This approach is also the main limit to be taken into account when interpreting the results. The experimental activities proposed in the verification and validation plan were not carried out during the internship and no test results are presented in the thesis. The contribution consists in their identification and methodological organization based on the characteristics of the devices, the risks and the documentation requirements already analyzed. Consequently, the actual closure of the gaps must be confirmed through the company documentation in force, the final definition of the configurations and, where necessary, the execution of the required checks.

Future developments concern first and foremost the completion of the technical activities that are still open. For IMT19 this means consolidating the configuration associated with new therapies and completing the relevant verifications, including performance aspects, sanitation, compatibility of accessories, software and other applicable tests. For VT16/VTH16, verifications of wet safety, sensors, hydraulic and pneumatic circuit, structural resistance, disinfection, VTH16 port and ozone when present shall be confirmed. In both cases, the results must be reported in risk management, GSPR checklist and in the verification and validation documents with unique and controlled references.

A second development concerns the clinical and post-market part. CEP, CER, PMS, PMCF and PSUR must remain consistent with the intended purpose, the claims maintained and the configurations placed on the market. Data from user experience, complaints, vigilance, literature and PMCF activities should be used to periodically review benefit-risk balance, residual risks, instructions for use and any need for modification. This is particularly important for IMT19 if new therapies are included in the final configuration, because it will require to distinguish, as far as possible, post-market information relevant to the different treatment modalities.

Finally, the path must be supported by a document management system capable of controlling versions, modifications, suppliers, non-compliance and CAPA. The conformity assessment with the notified body, where provided for by the class and procedure chosen, represents a time of verification of the system, but does not conclude the regulatory cycle. Conformity maintenance depends on the manufacturer's ability to update evidence over time and to maintain consistency between the actual product, technical documentation and data collected after placing on the market.

Overall, the case study highlights the role of the biomedical engineer as a link between technical, regulatory, clinical and quality aspects. In the context analyzed, the value of the activity lies not only in the drafting of new documents, but in the construction of verifiable links between requirements, risks, tests and responsibilities. This approach makes the technical file an operational tool to govern the device throughout its life cycle and provides a reusable basis for completing the MDR adjustment of the examined devices.

References

[1] European Parliament and Council of the European Union. Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union, L 117, 5 May 2017.

https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

[2] European Parliament and Council of the European Union. Regulation (EU) 2020/561 of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of some of its provisions. Official Journal of the European Union, L 130, 24 April 2020.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0561

[3] European Parliament and Council of the European Union. Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices. Official Journal of the European Union, L 80, 20 March 2023.

https://eur-lex.europa.eu/eli/reg/2023/607/oj/eng

[4] European Commission, Directorate-General Health and Food Safety. Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 – Extension of the MDR transitional period and removal of the "sell-off" periods. 2023.

https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a_1.pdf

[5] Medical Device Coordination Group. MDCG 2021-25 – Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC. Updated 2024.

https://health.ec.europa.eu/document/download/cbb11a6e-f0f3-4e30-af5e-990f9ef68bc1_en?filename=md_mdcg_2021_25_en.pdf&prefLang=lt

[6] Medical Device Coordination Group. MDCG 2021-24 rev.1 – Guidance on classification of medical devices. 2026.

https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf

[7] European Commission. Manufacturers of devices without an intended medical purpose. Public Health portal, Medical Devices section.

https://health.ec.europa.eu/medical-devices-topics-interest/reprocessing-devices/manufacturers-devices-without-intended-medical-purpose_en

[8] Medical Device Coordination Group. MDCG 2023-5 – Guidance on qualification and classification of Annex XVI products. 2023.

https://health.ec.europa.eu/system/files/2023-12/mdcg_2023-5_en.pdf

[9] European Commission. Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745.

https://eur-lex.europa.eu/eli/reg_impl/2022/2346/oj/eng

[10] International Organization for Standardization. ISO 14971 – Medical devices – Application of risk management to medical devices. Latest edition applied in the company context.

https://www.iso.org/standard/72704.html

[11] International Electrotechnical Commission. IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

https://webstore.iec.ch/en/publication/67497

[12] International Electrotechnical Commission. IEC 60601-1-2 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.

https://webstore.iec.ch/en/publication/67554

[13] International Organization for Standardization. ISO 15223-1:2021/Amd 1:2025 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

https://www.iso.org/standard/86270.html

[14] UNI. UNI 10865 – national standard relevant to the spa device context.

https://store.uni.com/uni-10865-2000

[15] Carbajo JM, Maraver F. Sulphurous Mineral Waters: New Applications for Health. Evidence-Based Complementary and Alternative Medicine, 2017;8034084. doi:10.1155/2017/8034084.

https://doi.org/10.1155/2017/8034084

[16] Varricchio A, Brindisi G, Brunese FP, et al. Thermal water inhalation for allergic rhinitis and recurrent respiratory infections: a narrative review of the evidence. Italian Journal of Pediatrics, 2025;51:290.

https://doi.org/10.1186/s13052-025-02133-1

[17] Franz L, Manica P, Claudatus J, Frigo AC, Marioni G, Staffieri A. Sulfurous-arsenical-ferruginous thermal water nasal inhalation and irrigation in children with recurrent upper respiratory tract infections: Clinical outcomes and predictive factors. American Journal of Otolaryngology, 2021;42:103083. doi:10.1016/j.amjoto.2021.103083.

https://doi.org/10.1016/j.amjoto.2021.103083

[18] Fesyun AD, Solimene U, Lobanov AA, et al. Mineral water inhalations for bronchial asthma: a meta-analysis. European Journal of Translational Myology, 2023;33(2):11460. doi:10.4081/ejtm.2023.11460.

https://doi.org/10.4081/ejtm.2023.11460

[19] Velepić M, Manestar D, Perković I, Škalamera D, Braut T. Inhalation Aerosol Therapy in the Treatment of Chronic Rhinosinusitis: A Prospective Randomized Study. Journal of Clinical Pharmacology, 2019;59(12):1648–1655.

https://doi.org/10.1002/jcph.1471

[20] Viegas J, Cardoso EM, Bonneau L, et al. A Novel Bionebulizer Approach to Study the Effects of Natural Mineral Water on a 3D In Vitro Nasal Model from Allergic Rhinitis Patients. Biomedicines, 2024;12:408. doi:10.3390/biomedicines12020408.

https://doi.org/10.3390/biomedicines12020408

[21] Ottaviano G, Marioni G, Staffieri C, et al. Effects of sulfurous, salty, bromic, iodic thermal water nasal irrigations in nonallergic chronic rhinosinusitis: a prospective, randomized, double-blind, clinical, and cytological study. American Journal of Otolaryngology, 2011;32(3):235–239.

https://doi.org/10.1016/j.amjoto.2010.02.004

[22] Keller S, König V, Mösges R. Thermal Water Applications in the Treatment of Upper Respiratory Tract Diseases: A Systematic Review and Meta-Analysis. Evidence-Based Complementary and Alternative Medicine, 2014;943824.

https://doi.org/10.1155/2014/943824

[23] Fermo S, Frosolini A, Parrino D, et al. Eustachian tube insufflation with thermal water: Effectiveness in the treatment of pediatric otitis media with effusion. American Journal of Otolaryngology, 2022;43(4):103504.

https://doi.org/10.1016/j.amjoto.2022.103504

[24] Arick DS, Silman S. Treatment of otitis media with effusion based on politzerization with an automated device. ENT–Ear, Nose & Throat Journal, 2000;79(4).

https://doi.org/10.1177/014556130007900416

[25] Costantino M, Lampa E, Nappi G. Effectiveness of sulphur spa therapy with politzer in the treatment of rhinogenic deafness. Acta Otorhinolaryngologica Italica, 2006;26:7–13.

https://pmc.ncbi.nlm.nih.gov/articles/PMC2639955/

[26] Mesolella M, Iorio B, Ricciardiello F, Motta G. Efficacy of crenotherapy by Politzer in the treatment of otitis media with effusion in children with down syndrome. International Journal of Pediatric Otorhinolaryngology, 2020;130:109803. doi:10.1016/j.ijporl.2019.109803.

https://doi.org/10.1016/j.ijporl.2019.109803

[27] Zasadzińska-Stempniak K, Karwat B, Jarmołowicz-Aniołkowska N, Zajączkiewicz H. Resolution of Otitis Media with Effusion in Adults after a Three-Day Course of Treatment with a Manosonic Nebulizer–A Pilot Study. Medicina, 2023;59:201. doi:10.3390/medicina59020201.

https://doi.org/10.3390/medicina59020201

[28] Antonelli M, Pennacchi A, Pasquarella G, Moscoloni M, Mariani G, Borioni B. Inhalation therapy with sulfur-rich thermal water for rhinogenic deafness: a series of case reports. International Journal of Biometeorology, 2025;69:703–707. doi:10.1007/s00484-024-02841-z.

https://doi.org/10.1007/s00484-024-02841-z

[29] Lopes S, Morgado S, Gomes ATPC, et al. Unravelling the benefits of thermal waters enhancing oral health: a pilot study. BMC Oral Health, 2024;24:1502. doi:10.1186/s12903-024-05278-3.

https://doi.org/10.1186/s12903-024-05278-3

[30] AlMoharib HS, AlAskar MH, AlShabib A, et al. The effectiveness of dental water jet in reducing dental plaque and gingival bleeding in orthodontic patients: a systematic review and meta-analysis of randomized clinical trials. International Journal of Dental Hygiene, 2024;22(1):56– 64.

https://doi.org/10.1111/idh.12741

[31] Nasermoaddeli A, Kagamimori S. Balneotherapy in Medicine: A Review. Environmental Health and Preventive Medicine, 2005;10:171–179.

https://doi.org/10.1007/BF02897707

[32] Péter I, Jagicza A, Ajtay Z, et al. Balneotherapy in Psoriasis Rehabilitation. In Vivo, 2017;31:1163–1168. doi:10.21873/invivo.11184.

https://doi.org/10.21873/invivo.11184

[33] Carpentier PH, Blaise S, Satger B, et al. A multicenter randomized controlled trial evaluating balneotherapy in patients with advanced chronic venous insufficiency. Journal of Vascular Surgery, 2014;59:447–454. doi:10.1016/j.jvs.2013.08.002.

https://doi.org/10.1016/j.jvs.2013.08.002

[34] Froldi M, Piana M, De Luca S, Nappi G. Combination of ozonated saline-bromine-iodine hydromassage and intermittent pneumatic compression in the treatment of lower-limb lymphoedema. Medicina Clinica e Termale, n.d.

https://www.researchgate.net/publication/289146677_Combined_salty-bromoiodic_hydromassage_and_intermittent_pneumatic_compression_in_the_treatment_of_lower_limbs_lymphedema

[35] International Organization for Standardization. ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories.

https://www.iso.org/standard/66912.html

[36] International Organization for Standardization. ISO 10993 series – Biological evaluation of medical devices.

https://www.iso.org/committee/54508/x/catalogue/

[37] International Electrotechnical Commission. IEC 62304 – Medical device software – Software life cycle processes.

https://webstore.iec.ch/en/publication/22794