VDE Recommendation

MD Comp

A practical framework to integrate non-medical devices and medical devices in a compliant way

VDE DGBMT

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Summary

As part of the “Connected Health” initiative, launched by the German Society for Biomedical Engineering (DGBMT) and the “The Information Technology Society in VDE” (ITG), the 6G Platform Germany, and the BMBF granted research project *Holistic Development of High-Performance 6G Networking for Distributed Medical Technology Systems (6G-Health)*, the objective of a significant improvement in health- and patient care, a reduction of healthcare costs, and fostering innovation by combining the high-speed, low-latency, and reliable communication are addressed. Alongside Beyond 5G and Sixth-Generation (6G) enabling technologies, the integration of a variety of medical and non-medical devices is a key factor in satisfying these requirements. However, as such integration demands compliance with a comprehensive regulatory ecosystem to maintain the efficacy, safety and quality of the incorporated medical devices, the main challenge is to harmonize the technical specifications of non-medical devices, such as IT devices, with the strict regulatory requirements for medical devices.

This recommendation for an *MD Comp* framework proposes a practicable solution to meet these requirements.

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Contents

1. Abstract

The medical sector and the field of medical technology, including medical devices, is a constantly growing sector: the global revenue of the medical technology sector is projected to reach USD 610.20 billion in 2024, with medical devices expected to dominate with a projected market volume of USD 511.20 billion in 2024 [3]. This industry is globally characterized by the continuous development of innovative technologies and increasing connectivity. In particular, current developments in connectivity (6G) and artificial intelligence (AI) methods will accelerate this process.

The objective of this recommendation for a „Medical Device Compliant (*MD Comp*)" framework is to bring together an alignment of information technology (IT) together with non-medical equipment with stringent safety, security, and operational standards.

The document provides a comprehensive analysis of the requirements necessary to integrate medical and non-medical devices into (complex) systems within the regulatory framework.

The document presents also a comprehensive analysis of the challenges when integrating Medical and non-Medical devices to (complex) systems in the context of the medical device regulatory framework. It suggests as solution an innovative approach, the *MD Comp* (Medical Device-Compliant) framework, aligning IT and other non-medical equipment with the stringent safety, security, and operational standards applied to medical devices.

Key aspects of the document include a detailed examination of current regulatory landscapes, highlighting the necessity for such integration due to the increasing reliance on technology in healthcare. The proposal outlines methods to ensure that non-medical devices meet the high safety and cybersecurity standards required for medical equipment, thereby reducing risks to patient safety, and improving the overall efficacy of medical systems.

The document also delves into specific challenges and solutions related to this integration. It discusses the technological and regulatory hurdles that must be overcome and suggests practical steps for achieving compliance. Case studies are presented to illustrate the potential benefits and pitfalls of integrating non-medical devices into the medical regulatory framework.

2. Introduction and motivation

2.1. Why do we need MD Comp?

The integration of medical and non-medical devices within healthcare systems is a critical step towards the advancement of patient care, offering the potential to harness the capabilities of innovative technologies while ensuring patient safety and compliance with stringent medical regulations. The *Medical Device Compliant (MD Comp)* approach described herein is an efficient and practicable attempt to accelerate and streamline the integration process. The proposal is mainly the result of concepts developed as part of the *Connected Health* initiative, started by the German Society for Biomedical Engineering (DGBMT) and The Information Technology Society in VDE (ITG) in cooperation with the 6G Platform Germany, and the BMBF granted project *Holistic Development of High-Performance 6G Networking for Distributed Medical Technology Systems (6G-Health)*.

2.2. What gap can be closed by the MD Comp Framework?

Consider the case of remote patient monitoring, a healthcare application that has gained significant traction in recent years. Patients with chronic conditions, such as diabetes or heart disease, often require continuous monitoring to manage their health effectively. Traditional monitoring systems involve frequent visits to healthcare facilities, which can be inconvenient and costly. With the progression of technology, the potential for real-time, high-speed, and low-latency communication opens new possibilities for remote monitoring, allowing patients to be monitored at home while providing healthcare professionals with immediate access to critical health data. However, the integration of non-medical devices, such as consumer-grade sensors and IT equipment, in process chains with medical devices poses a regulatory and safety challenge, if the overall system is used for patient diagnosis, prevention, monitoring, prognosis or therapy. These non-medical devices are typically not designed to meet the rigorous standards required for medical applications, such as those outlined in the European Medical Device Regulation (MDR) [1]. The *MD Comp* framework addresses this gap by pre-aligning non-medical devices with medical standards, thereby facilitating their integration into medical systems without becoming a regulatory bottleneck.

The *MD Comp* framework is a “compliance by design” approach that applies selected requirements from medical technology to non-medical products, qualifying them as medical device compliant.

This framework ensures that non-medical devices are designed to fulfill specific medical device requirements, thus enabling seamless integration and safe operation within medical systems. The *MD Comp* label implies a market advantage, as these devices are likely to be the preferred choice for medical applications due to their compliance with safety and cybersecurity requirements.

2.3. What is the scope of the MD Comp Framework?

Today’s medical systems often contain medical and non-medical devices (see Fig. 1). As mentioned above, in such case the manufacturer of the MD or the system-integrator must assess the implications in his conformity assessment process. He must perform a risk analysis to determine if and under which conditions the non-MD may be used in the system.

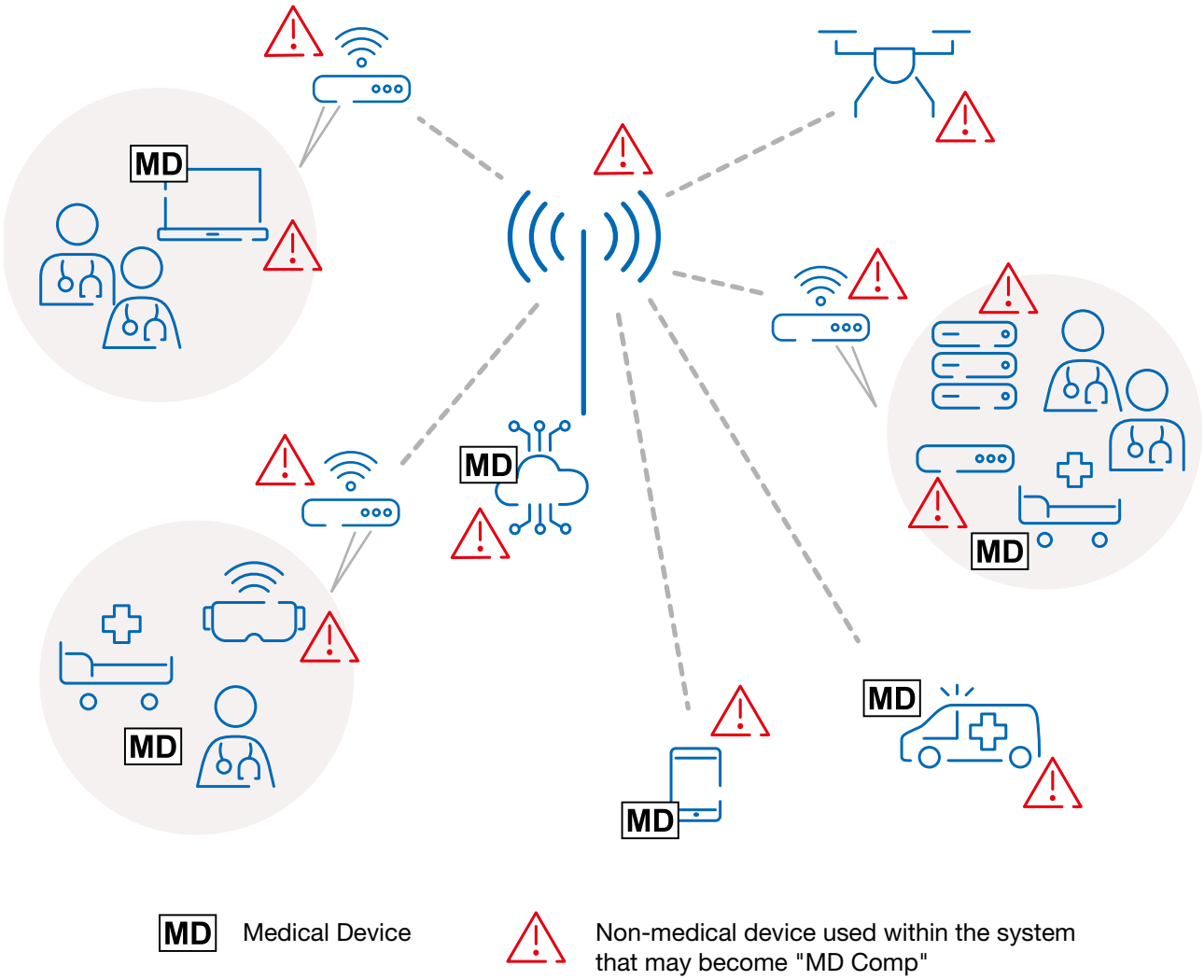

Fig. 1: Complex system, containing medical (MD) and other devices

The medical device industry is a highly regulated sector, with medical devices being subject to rigorous regulatory requirements to ensure patient safety and device performance. In Europe, the MDR [1] outlines the requirements for placing medical devices to market, including clinical evaluations, risk assessments, and quality control measures. Non-medical devices, while also regulated for safety, do typically not undergo the same high level of requirements, including clinical assessment.

Regarding the current situation in healthcare, a clear trend becomes visible: a significant shift towards connected systems. This reflects a trend towards interoperability and the creation of technological ecosystems where devices do not function in isolation but as interconnected networks.

To address these challenges and to facilitate the seamless integration of such products in complex systems, we propose a framework in which non-medical devices are designed in such a way that they already meet selected specific requirements of medical devices. Such components are referred to as *MD Comp*.

The designation *MD Comp* goes beyond certification. It stands for a commitment to comply with applicable criteria of the (often) stricter standards in medical technology. *MD Comp* embodies a set of well-defined criteria ensuring that non-medical devices can be easily combined with medical devices and operate seamlessly within medical systems. Such products and systems ensure safety in addition to cybersecurity requirements by addressing the requirements detailed below.

This document outlines the approach of the *MD Comp* framework when combining devices. Through a comprehensive review of existing literature, an analysis of applicable guidelines, and an examination of real-world case studies and demonstrators, a practical approach is proposed that complies with regulatory requirements. The *MD Comp* framework provides leadership in mitigating risk and bridging the technical and regulatory gap.

2.4. Differentiation of accessory MDR and accessory in general

The definition of the term "Accessory" in the context of the MDR [1] differs significantly from the general meaning of the word "accessory". In the context of medical devices, "Accessory" refers specifically to items or software intended to be used with a medical device to *"specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)"*.

One challenge from a regulatory perspective is that *MD Comp* products shall not qualify as accessories for a medical device. In particular, *MD Comp* products must be distinguished from accessories for a medical device that merely support the functionality of the respective medical device. Here, the support function within the definition of an accessory according to Article 2 No. 2 MDR [1] – "specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)" – shows that the definition must be interpreted narrowly in a sense that not every facilitation or assistance of the use of a medical device is sufficient to qualify a product as an accessory under the MDR [1].

In this context, it must be made clear that *MD Comp* products still only have a general purpose and merely provide certified interfaces for the interoperability with medical devices in IoT-environments but are not intended to specifically and directly support the intended purpose of medical devices connected to *MD Comp* devices.

In order to support a clear and legally secure distinction at the borderline between accessories and non-medical products qualifying as medical device compliant, we suggest establishing a guidance, as in the the existing "Manual on Borderline and Classification for Medical Devices" under MDR [1] and In Vitro Diagnostic Regulation (IVDR) [2] published by the EU Commission. At a later stage, a revision of the MDR [1]/ IVDR [2] should clearly address the issue of complex IoT-environments containing medical devices and non-medical devices with a focus on criteria to differentiate between accessory and *MD Comp* products which are not regulated within the framework of the MDR [1].

2.5. Regulatory landscape

Remark: in the following context, "medical device" refers to both, IVDR and MDR. The term "Medical Device" elaborates mainly on MDR but must be seen within the context of IVDR, too.

2.5.1. Medical

Medical devices
In Europe, medical devices and their accessories are subject to the legal requirements of the European Medical Device Regulation (EU)2017/745 (MDR) [1] and In-vitro Diagnostic Medical Devices Regulation (IVDR) [2]. Furthermore, the manufacturer must deal with relevant guidelines and technical standards [4][5]. Certain areas of legal provisions, such as criminal law and operator law, remain under the sovereignty of the EU member states and are regulated in Germany, for example, by the Medical Devices Implementation Act (Medizinprodukterecht-Durchführungsgesetz, MPDG) [6]. In addition, there are requirements derived from horizontal EU legislation (e.g., Data Protection Regulation 2016/679 (GDPR, [7]) or the Radio Equipment Directive 2014/53/EU [8].

Medical device manufacturers must fulfill the general obligations listed in Art. 10 MDR. The first obligation in Art. 10 [1] requires that medical devices "have been designed and

manufactured in accordance with the requirements of this Regulation". This includes, among other things, compliance with the General Safety and Performance Requirements (GSPR) according to Annex I MDR. However, the manufacturer must identify the relevant requirements for the respective device [9]. Other requirements concern, among other things, quality management, risk management, clinical evaluation, instructions for use and labeling, as well as technical documentation.

Accessory

Accessory is defined in Art. 2 (2) MDR as *"an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)"*. In general, accessories are treated as independent medical devices due to the provisions in No. 3.2 Annex VIII MDR. Thus, for accessories the conformity with the applicable GSPR must be assessed. This also applies regarding the use with the respective specified medical device(s). Moreover, not only the medical device but also its accessories shall be described in the technical documentation (No.1.1. (h) Annex II MDR).

Systems or procedure packs

Systems or procedure packs both combine products to achieve a specific medical purpose (Art. 2 (10) and (11)). If this combination covers devices, "which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose […]", these must comply with the regulatory requirements for medical devices (Art. 22 (4) MDR). In general, this requirement has a legal effect on non-CE-marked products (i.e., not qualified as a medical device or accessory to a medical device) that are to be used together with medical devices and their accessories. Thus, it is in the sole responsibility of the medical device manufacturer to ensure the safety and performance of such non-CE-marked products.

Hardware or hardware component as integral part of a general consumer product

The Medical Device Coordination Group (MDCG) published in October 2023 the guidance MDCG 2023-8 on Medical Device Software (MDSW) that is intended to work in combination with hardware or hardware components [10]. According to this guidance two basic scenarios are conceivable:

1. the MDSW interacts with a hardware (component) that is a medical device or an accessory to a medical device from the same or another manufacturer or
2. the MDSW interacts with a hardware (component) that is neither a medical device or an accessory to a medical device from the same or another manufacturer.

A typical example for a hardware component of the scenario 2 is the photoplethysmogram (PPG) sensor of the Apple Watch that provides pulse rate data for the Irregular Rhythm Notification Feature (IRNF) mobile App [11]. This sensor is neither a hardware component from a medical device nor an accessory to a medical device, but the IRNF app is recognized as MDSW in Europe and the United States [12]. The MDCG guidance emphasizes that in scenario 2 "the MDSW manufacturer is not able to rely on the compliance and conformity of the hardware or hardware component with the MDR". Thus, the manufacturer must ensure "the safety, performance and reproducibility of the hardware or hardware component [e.g., the PPG sensor of the Apple Watch) in its combined use with the MDSW in all intended configurations." This shall be achieved for products not qualified as a medical device or accessory by:

1. Comprehensive description and specification in the technical documentation of the respective medical device (No. 1.1 Annex II MDR),
2. Managing and controlling risks of all combined products (No. 3-5 Annex I MDR), including inherent safety by design,
3. Demonstration of clinical evidence (i.e., clinical data and clinical evaluation results, which prove the safety and clinical benefits (Art. 61 MDR)) for all intended configurations, and
4. Post-market surveillance with "adequate controls, by which the proper function of the hardware or hardware component can be monitored."

The implications for risk management are also addressed in Annex G of ISO TR 24971 [13]. Accordingly, several aspects regarding the risk management plan and file are discussed. Although the guideline MDCG 2023-8 addresses specifically MDSW, the requirements and principles described herein may also apply to other combinations of medical devices and products not qualified as a medical device or accessory.

2.5.2. Non-Medical

Radio equipment

The process of placing products on the market is described and embedded in the elements of the New Legislative Framework (NLF). Derived from the NLF structure, it is required that any product that is made available on the EU market must be accompanied by one single EU Declaration of Conformity (EU DoC) which must contain any applicable part of EU law to the equipment. Radio Equipment Directive (RED) [8], published as EU Directive no. 2014/53/EU, considers any product that "intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination" to be radio equipment. To avoid redundancies in the citation of legislation, some Directives like EMC Directive and Low Voltage Directive are formally excluded from the compliance statement but referenced within the essential requirements. Others, like MDR are not excluded and therefore also applying. Thus, products composed of i.e., medical devices and radio products are considered to be both, medical device and radio equipment, and must follow the requirements of MDR and RED, likewise.

Essential requirements

RED article 3 sets out four classical essential requirements demanding for compliance regarding product safety, electromagnetic compatibility (EMC), radio spectrum as well as health requirements. The latter refers to general exposure of radio products towards human beings, not reflecting specific requirements for products in medical applications.

While the radiocommunications compliance of medical devices can be demonstrated by applying the relevant test standards according to the radio technologies used, the demonstration of compliance with product safety, EMC and health requirements is much more complex. This is because the intended use of the device is central to the overall compliance of the device. In the context of medical applications, the intended use may therefore entail specific requirements derived from the medical requirements, which may not be covered by a common conformity assessment according to the rules of RED.

A common approach when integrating radio products into medical devices is to separate the requirements of the radio component from the medical device. For the radio part, it is normally not complex to define which technologies are used and the applicable standards for the radio technologies can be found quite quickly by investigating radio test standards issued by European Telecommunications Standards Institute (ETSI). There might be several cases where specific or proprietary radio technologies are applied in the absence of radio test standard addressing this technology. In these cases, generic standards covering any regulated frequency spectrum range can be used to prove radio compliance.

The essential requirements of product health against the RED can also be met by the application of pertinent procedures to demonstrate electromagnetic field or radio frequency exposure towards human beings. This is normally done by using radio frequency exposure calculations which are based on the exposure limits set of in ICNIRP guidelines [14]. A more complex but very popular procedure for body-worn devices is SAR, where SAR stands for Specific Absorption rate measuring the temperature rise of a characteristic part of human tissue by applying a radio field in close proximity.

The product safety and EMC compliance are certainly the most critical part of demonstrating compliance according to RED when medical devices are in focus, because of their own requirements on these aspects. Usually, product safety and EMC requirements derived from the MDR are much more demanding than classical RED requirements for mainstream radio

products. Hence, the medical intended use demands stricter requirements. This means that for most medical devices, MDR compliance requirements for product safety and EMC can be leveraged to RED on the basis that these requirements already cover any RED requirements. However, as there is no guarantee that the requirements of the MDR will always be more stringent than those of the RED, the risk assessment shall reflect that any risk is covered by the most stringent measure, whether derived from the MDR or the RED.

Cybersecurity for radio products

The RED introduces new requirements regarding cybersecurity of radio equipment, applicable from 1 August 2025. These requirements are described in Article 3.3 d, e and f respectively and address the following aspects:

- (d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service
- (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected
- (f) radio equipment supports certain features ensuring protection from fraud.

Where part (f) is applicable for devices supporting monetary transfer only, parts (d) and (e) are applicable for internet-connected devices and devices supporting the processing of personal, traffic or location data. Besides these clear cases describing the applicability of the requirements, there are also exemptions, for example for devices that are body-worn or used for special purposes like childcare. Harmonized standards addressing Article 3.3 (3 d, e, f) are currently under development but not available at this time.

Regarding the underlying legislation for medical devices, it is important to note that devices under the scope of the MDR and IVDR are exempted from the cybersecurity requirements defined in the RED.

MD Comp in the radio context

The practical approach of merging radio components with medical devices is therefore based on a distinguished assessment of medical requirements on the one hand and radio requirements on the other hand, taking into account delta-evaluation of the scenarios where radio parameters influence the medical use of the device and vice versa. Often devices are already pre-tested regarding MDR requirements before radio compliance is considered. Thus, the considerations described above take place at a later stage, typically starting with a complete radio test of the applied radio technologies and delta-evaluation regarding EMC and safety aspects. Here, the proposed *MD Comp* framework will make the specific requirements more transparent and reduce the risk of non-compliance, especially in the early phase of selecting appropriate radio components for medical application.

2.6. Implications and challenges

Combining medical and non-medical devices requires that manufacturers / system integrators must carefully consider the regulatory requirements and practical challenges of such a combination. We recommend considering this as early as possible in the development system integration process to ensure compliance and to address any potential issues proactively. In this chapter, the challenges are described when combining medical and non-medical devices.

Classification:

- The combined product may need to be classified as a medical device, depending on the medical purpose is its primary function.
- If the non-medical function could affect the safety or performance of the medical function, the entire product might be subject to medical device regulation.
- If the product contains radio functions, RED compliance shall be ensured on module level and verified on the final product (host level)
- This implies that the manufacturer of the medical device or the system-integrator includes the non-medical device in the risk analysis considerations.

Compliance:
- The system (incorporating medical and non-medical devices) will need to comply with the Medical Device Regulation (MDR) or In Vitro Diagnostic Regulation (IVDR)
- Depending on the scope and extent of the integration, a conformity assessment may be required for the whole system.
- In a “worst case scenario”, the non-medical device will need to undergo an assessment of conformity according MDR.

Technical documentation:
- Technical documentation is required to demonstrate that a device meets relevant regulatory standards and requirements.
- It provides detailed information for conformity assessment and includes (among others) a detailed description of design, risk management, manufacturing documentation, performance considerations, tests, validation.

Electromagnetic disturbances (EMC):
(if the products are electrically operated)
- Medical devices must be compliant with the applicable IEC and ISO standards, such as IEC 60601-1-2 [17].
- Non-medical devices must comply with their applicable IEC and ISO standards, considering EMC.
- If non-medical devices are combined with medical devices as a system, further considerations need to be made to ensure the safe and effective functioning of the system.
- Such assessment includes evaluation if the non-medical device could adversely affect the medical device. In such a case, the non-medical device must fulfill the same requirements and must be tested in the same way as the medical device. See IEC 60601-1-2, clause 4.2 [17].
- Additional requirements for radio equipment may be applicable.

Involvement of notified bodies:
- If a conformity assessment of such non-medical device is required, depending on the classification, a Notified Body (NB) may need to be involved in the assessment.
- If radio equipment is integrated into the medical device and the radio technologies that are applied cannot be evaluated using harmonized EN standards, RED requires to involve a RED NB additionally.

Risk management:
- The manufacturer must conduct a comprehensive risk assessment for the combination of the devices, considering interactions between the medical and non-medical components.
- These risk-management activities involve a high level of effort, as the specifications of the non-medical product are not known in detail.
- RED risk assessment requires to consider specific risks for the radio spectrum if radio components are used.

IT-Security / Cybersecurity:
- The MDR [1] requires considering IT-security in the GSPR.
- As the GDPR emphasizes on “data concerning health” being particularly sensitive data ([7] Art.9), risk management must take this into consideration.

Clinical evaluation:
- A clinical evaluation may be necessary to assess the safety and performance of the system after incorporating non-medical devices.

Design and manufacturing:
- The design and integration process must ensure that the non-medical component does not adversely affect the medical components in the system.
- The intended use of the medical devices must be considered, and it must not be adversely affected by establishing the combination.
- The integration processes must meet the stringent requirements for medical devices (which may not have been necessary for the non-medical component alone).

Traceability:

- Traceability and unique device identification (UDI) in medical devices ensure that patients receive the correct devices for their treatments, significantly reducing the risk of errors and improving overall care quality.
- These systems allow for the rapid and precise identification and tracking of medical devices, facilitating quicker and more effective recall processes in case of malfunctions or safety issues.
- Traceability and UDI support regulatory compliance by providing detailed data on device use and performance, which is crucial for post-market surveillance and informing future medical device developments.

User training and instructions:

- Instructions for use and user training materials must be provided.
- There may be a need for additional information due to the combined functionalities.
- Some legislation, i.e. RED, define additional requirements for the accompanying documents and the contained information.

Marketing and labeling:

- Labeling requirements for medical devices are strict, and the system must adhere to these, potentially affecting the non-medical component.

Post-market surveillance:

- The manufacturer / system integrator must monitor the performance and report any incidents or corrective actions, as required for medical devices.

Liability and insurance:

- Combining a medical and non-medical device could change liability risks.
- The documentation must be transparent enough to retrace conformity assessment back to module level in order to address liability aspects in case of non-conformity *MD Comp* Framework

3. MD Comp Framework

We suggest a framework, based on the state-of-the-art requirements for medical devices. The framework focuses on safety and security and omits medical-device-specific characteristics, such as characteristics related to a specific clinical purpose because a non-medical device has no clinical purpose. This framework can be applied to non-medical devices (or non-medical components) creating a novel category of devices / components, named *MD Comp*.

After applying the described framework, the devices / components comply with certain medical device requirements. The regulatory burden for integrating it into a medical system is significantly reduced.

This pre-alignment with medical standards means that both, manufacturers and system integrators, can focus on the additional requirements specific to the medical application of the system. This significantly streamlines the process of obtaining regulatory compliance as the non-medical device component does not become a regulatory bottleneck. Further, the label *MD Comp* may imply a market advantage and such devices / components are likely to be the preferred choice for use in such context.

However, being a *MD Comp* device / component does not imply that the components can be combined without further assessment, regarding the implications that may arise with the final configuration.

3.1. Example application of the MD Comp framework to IEC 60601-1

The following table shows as an example the application of the *MD Comp* framework to selected chapters of IEC 60601-1 [15]. In continuation of the considerations presented here, further standards and technical reports have to be taken into account, such as ISO 14971 [16] and ISO/TR 24971 [13]. Though IEC 60601-1 [15] covers Programmable Electrical Medical System (PEMS) in chapter 14, IEC 62304 [18] has to be considered, too, in case software is present in the device(s). In Appendix B the application of the proposed framework is shown. Fig. 2 illustrates the application of the framework.

Example of the application of the *MD Comp* framework to selected chapters of IEC 60601-1 ✓: The requirements of the applied standard are fully applicable (✓): The requirements of the applied standard are applicable in general; patient-related content is omitted. P: Manufacturer of the *MD Comp* device provides information upon request			Usage Environment / Device Attributes						
Selected chapters of IEC 60601-1	**General (always required)**	**Usage in the Patient Environment**	**In direct contact with the patient**	**Contains Radio-Equipment (WiFi / Bluetooth, ...)**	**Handles or routes patient data / Personal Identifiable Information**	**Has external Power Supply**	**Contains Batteries / Internal Power Supply**	**Incorporates Software / PEMS**
4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)
4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT			✓					
4.7 SINGLE FAULT CONDITION for ME EQUIPMENT	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	
4.10 Power supply						✓	✓	
6.2 Protection against electric shock						✓	✓	
6.3 Protection against harmful ingress of water or particulate matter		✓	✓			✓	✓	
6.4 Method(s) of sterilization			✓					
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT		✓	✓					
6.6 Mode of operation	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	
7 ME EQUIPMENT identification, marking and documents	✓	✓	✓	✓	✓	✓	✓	✓
7.9 ACCOMPANYING DOCUMENTS	✓	✓	✓	✓	✓	✓	✓	✓
8 Protection against electrical HAZARDS from ME EQUIPMENT		P	P			✓	✓	
8.1 Fundamental rule of protection against electric shock		P	P			✓	✓	
8.4 Limitation of voltage, current or energy		P	P			✓	✓	
8.5 Separation of parts		P	P			✓	✓	
8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT		P	P			✓	✓	
8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P	P			✓	✓	
8.8 Insulation		P	P			✓	✓	
8.9 CREEPAGE DISTANCES and AIR CLEARANCES		P	P			✓	✓	
8.10 Components and wiring		P	P			✓	✓	
8.11 MAINS PARTS, components and layout		P	P			✓	✓	
9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS		P	P					

Tab. 1: Requirements depending on the conditions of use or device attributes

Example of the application of the *MD Comp* framework to selected chapters of IEC 60601-1 ✓: The requirements of the applied standard are fully applicable (✓): The requirements of the applied standard are applicable in general; patient-related content is omitted. P: Manufacturer of the *MD Comp* device provides information upon request **Selected chapters of IEC 60601-1**	**General (always required)**	**Usage Environment / Device Attributes**						
		Usage in the Patient Environment	**In direct contact with the patient**	**Contains Radio-Equipment (WiFi / Bluetooth, ...)**	**Handles or routes patient data / Personal Identifiable Information**	**Has external Power Supply**	**Contains Batteries / Internal Power Supply**	**Incorporates Software / PEMS**
10 Protection against unwanted and excessive radiation HAZARDS		P	P					
11 Protection against excessive temperatures and other HAZARDS		P	P			✓	✓	
11.2 Fire prevention		P	P			✓	✓	
11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT		(✓)	(✓)					
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS		(✓)	(✓)					
11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT						✓	✓	✓
12 Accuracy of controls and instruments and protection against hazardous outputs		P	P					P
13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)	(✓)
13.2 SINGLE FAULT CONDITIONS	✓	✓	✓	✓	✓	✓	✓	✓
14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	P			P	P	P	P	✓
15 Construction of ME EQUIPMENT	P	P	P	P	P	P	P	
15.3 Mechanical strength		(✓)	(✓)					
16 ME SYSTEMS	✓	P	P	P	P	P	P	P
16.1 General requirements for the ME SYSTEMS	✓	P	P	P	P	P	P	
16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM	✓	P	P	P	P	P	P	P
16.3 Power supply	P					✓	✓	
16.4 ENCLOSURES	P	✓	✓					
16.5 SEPARATION DEVICES	P					✓	✓	
16.6 LEAKAGE CURRENTS	P					✓	✓	
16.7 Protection against MECHANICAL HAZARDS	P	✓	✓					
16.8 Interruption of the power supply to parts of an ME SYSTEM	P					✓	✓	✓
16.9 ME SYSTEM connections and wiring	P	P	P			✓		

Tab. 1 continued

3.2. Explanation of the basic procedure

3.2.1. Defining criteria for MD Comp certification

Non-medical devices, designed for general consumer use, typically prioritize functionality, user experience, and cost-effectiveness. In contrast, medical devices adhere to a higher standard, concerning safety and clinical performance.

In order to use non-medical devices in systems containing medical devices, we suggest elevating such non-medical devices to a higher level in order to make them more compatible with medical devices. This may necessitate significant modifications to meet medical standards.

As starting point, [19] describes common specifications for specific products as listed in [1] Annex XVI. Such products shall address, at least, the application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety.

While this approach certainly addresses the key issues, it appears appropriate to describe the requirements in greater detail.

3.2.2. Applying basic technical standards

In the field of medical devices, the primary safety standard is IEC 60601-1 [15]. Compliance with this standard is essential for ensuring safety and performance of medical electrical equipment. It contains requirements, governing design, testing, accompanying documents etc. Following this standard is not just best practice but a regulatory requirement as it defines the level of safety that can be expected.

For this reason, some of the key concepts of this standard are described below.
We suggest applying these concepts within the *MD Comp* Framework.

Single Fault Safety / Risk Management
Single Fault Safety and Risk Management are key elements in the design and operation of medical devices and systems. This concept describes that a device remains safe even in case a single fault condition or a single failure occurs. Risk Management takes this approach even further as it involves identifying potential hazards, assessing their likelihood and impact, followed by implementing strategies to minimize these risks. We suggest applying this concept in such a way that the components contribute to risk management by providing likelihood-considerations, such as likelihoods for failures. Based on this information, the system integrator can perform his risk management as he knows about the usage of the device and the related severity. This interaction makes the risk management in the system-context complete.

Mechanical strength
Mechanical safety describes the aspect of structural integrity, including operational reliability of mechanical components. A key aspect of mechanical safety is mechanical strength which describes the ability of a component or system to withstand operational stresses and external forces without failure or deformation. We suggest applying the concepts, taking the operational environment of medical devices into account.

Sharp Edges / Corners, Moving Parts
Consideration of further mechanical hazards, specifically sharp edges/corners and moving parts, is of relevance as medical devices are often used in sensitive and vulnerable environments, such as operating rooms, clinics, and patient care settings. In these environments, the presence of sharp edges or corners can pose significant risks of injury to both patients and healthcare professionals. These injuries can range from minor cuts to more serious lacerations, potentially leading to infections or other complications. Moving parts in medical devices require careful design as improperly designed moving parts can lead to squeezing points or entrapment, resulting in (severe) injuries. These risks must be considered in

the situation where devices come into direct contact with patients, such as surgical tools, diagnostic equipment, and patient support systems. In addition, mechanical hazards can compromise the sterility and overall integrity of the clinical environment. Consider sharp edges, tearing gloves or protective coverings, leading to contamination risks.

Material Selection

Selecting adequate materials is a key issue in medical devices. Materials used in non-medical devices may not be biocompatible or sterilizable, two critical requirements for medical applications. If these materials are in contact with the human body, such materials must be non-toxic, hypoallergenic, and compatible with the human body to prevent adverse reactions. The above-mentioned material properties must be proven. Depending on the environment (e.g., in an operating theatre and the like), materials that can be disinfected have to be chosen. Cleaning agents may be aggressive and degrade the materials, used for the housing. The coating (if any) could also be affected.

Ingress of Liquids

In the operational field of medical devices, liquids are omnipresent. Consider blood, infusion solutions containing NaCl and the like. Ingress of such liquids can significantly compromise the safety of a medical device; electrical components can be damaged, or insulation may be short-circuited. Furthermore, liquid ingress can lead to contamination and hygiene issues. If liquids, particularly those containing biological materials like blood, penetrate the housing of a device, they can create a breeding ground for bacteria and other pathogens. Additional effects to be considered are corrosion or degradation.

Electric Shock

Electronic components used in non-medical devices often require upgrading. Medical devices demand a high level of protection against electrical hazards, such as protection against electric shock and protection against leakage currents. Especially mains power supplies must be considered. These requirements apply in case the non-medical devices are used in the patient environment and / or have a galvanic coupling into such environment, e.g. by means of a wire, connected on one end to an electrode that is applied to the patient and on the other end connected to the non-medical device. Further implications arise from the design of connectors. Medical devices have specific demands in this context. Reliability of components as well as accuracy needs also to be taken into consideration, as even “minor” malfunctions can have severe implications.

Adverse Temperatures

Adverse temperatures must be taken into consideration in the design, operation, and storage of medical devices. Environmental conditions may affect the functionality as electronic components, such as batteries, and certain materials may malfunction or degrade when subjected to temperatures outside operating range. This can lead to inaccurate readings, device failure, or unexpected behavior. Reliability may also be affected in long-term consideration. In case a device contains electronic components, surfaces may become too hot during use. Similarly, excessively cold devices can be uncomfortable and may adversely affect the medical procedure.

Batteries

Depending on the context of use, batteries and internal power supplies are critical components in the safety context. Batteries ensure continuous operation even without mains power supply. In scenarios like surgeries or intensive care, even a brief interruption in power can have severe implications. On the other hand, batteries need to be considered as they may overheat.

Electromagnetic Disturbances / Electromagnetic Compatibility

It must also be ensured that the device can be used within an environment with strict electromagnetic interference guidelines, set by medical authorities. Consider HF surgical equipment (providing interferences during their operation, disturbing the function of the non-medical device) as well as monitoring equipment (that may be interfered by the non-medical device and its emissions, leading to inaccurate measurements and in the consequence to possible patient harm.)

Software

Software in medical devices represents a critical component. Developing medical device software requires adhering to a sophisticated and well-documented development lifecycle, with a focus on process control as well as on testing and release.

Although software development processes were not originally invented for medical devices, adherence to such well-defined processes is crucial. These software-development-processes, including accompanying processes, such as risk management, problem resolution and configuration management, are defined in applicable standards and offer, while general in nature, a structured framework ensuring safety, reliability, and quality in medical device software. They provide a systematic approach to software design, development, testing, and maintenance.

Special attention must be given to AI/ML components and algorithms used in data processing and analysis, emphasizing precision and consistency. This might involve implementing advanced error detection and correction protocols, ensuring data privacy and security in line with healthcare regulations, and providing traceable records of device performance for audit purposes.

Cybersecurity

Cybersecurity is critically important in medical software. In case a non-medical device is used in a clinical context, the following should be considered.

- **Patient Safety:** Medical software often controls devices that directly affect patient health. A cyberattack could manipulate device functionality, leading to incorrect diagnoses, improper treatments, or even direct harm to patients.
- **Data Privacy and Confidentiality:** Medical software handles sensitive personal and health information. Breaches can lead to unauthorized access to patient records, violating privacy laws and eroding the trust between patients and healthcare providers.
- **Compliance with Regulatory Standards:** Depending on the regulatory context, the healthcare industry must follow strict regulatory requirements. In Europe, GDPR is evident, HIPAA (Health Insurance Portability and Accountability Act) in the United States. These regulations focus (among others) on the protection of patient data. Failure to comply with these regulations due to inadequate cybersecurity can result in significant legal penalties and financial losses. Loss of repudiation could be another consequence.
- **Operational Continuity:** Cyber-attacks like ransomware can challenge the availability of healthcare systems, preventing access to critical patient data and disrupting delivery of treatments, delaying, or preventing medical care. As such cyberattacks are often not addressed directly to medical devices but to the components in the system being “general IT components”, robust cybersecurity is essential to ensure availability and reliability of medical systems.

Usability

The overall design of medical devices must meet ergonomic and operational standards in a medical setting. In the specific context of a medical-device environment, the user interface becomes an important part in the safety-considerations. Non-medical devices may have to be considered ease of use, not only by healthcare professionals, but also by laypeople, depending on the context of use, ensuring that the device can be used effectively in a clinical setting. Features like emergency access, emergency shut-off or alarm systems have to be considered.

Instructions for use

The Instructions for Use (IFU) contains vital information to ensure safe, effective, and intended use.

In regulatory terms, the IFU is an MDR requirement. It plays a significant role in compliance with regulations and standards, helping manufacturers and healthcare providers meet legal obligations and avoid liabilities.

4. Benefits and Impact

4.1. Compliance by Design

By applying the described approach, the integration of non-medical devices into systems, containing medical devices, is significantly streamlined. The methodology focuses on interoperability and standardization, key factors that facilitate seamless device combination. When devices are designed with compatibility in mind, the non-medical devices can easily connect within the system, reducing the complexity typically involved in merging different technological approaches.

The burden of having to carry out individual conformity assessments or to include conformity-consideration when adding components to a complex system is significantly reduced. This simplifies the technical aspects of device integration and enhances the efficiency and effectiveness of the process. Users benefit from a more cohesive experience, with reduced setup times and fewer compatibility issues. Ultimately, this approach leads to a more user-friendly and efficient system.

4.2. Improvement of Conformity Assessment of Systems, containing both types of Devices

By applying the described approach, different device-types with different regulatory backgrounds can be easily connected. The conformity assessment process of the complex system becomes easier as the devices, although having a different regulatory background, have a comparable safety level or provide the necessary information to be able to assess the risks of such combination. This simplifies the conformity assessment considerably.

4.3. Enhanced Data Security and Compliance

The described approach enhances cybersecurity and compliance as cybersecurity considerations are regarded from the very beginning (compliance by design). By designing devices and software with a focus on data protection and privacy, risks such as unauthorized access, data breaches, and information theft are significantly reduced. The availability of components, supporting these important considerations, allows aligning with regulations, like GDPR [7] in Europe.

If the approach is followed, monitoring of the system and necessary security-updates against emerging cyber threats become easily achievable. Consequently, this proactive approach on data security and regulatory compliance ensures integrity and trustworthiness of patient care.

4.4. Improved Patient Care

By ensuring that different device-types with different regulatory backgrounds can easily connect and communicate, system integrators gain access to a wide range of versatile possibilities. Systems may be combined to support treatments tailored more effectively to individual patient needs. New opportunities for innovative medical solutions and care strategies become available. This interconnectedness allows data sharing and analysis, leading to quicker and more accurate diagnoses, more personalized treatment plans, and timely interventions. Moreover, the simplicity and reliability of such systems reduce the risk of errors and device malfunctions, thereby increasing patient safety. Overall, this holistic and streamlined approach to device integration not only improves the effectiveness of medical care, leading to better health outcomes and increased patient satisfaction.

5. Discussion and Recommendations

5.1. Anticipated Challenges

Introducing a novel approach to conformity assessment is likely to encounter challenges. We anticipate the following:

Resistance to Change
Resistance is likely if an existing system is called into question. People and organizations often prefer familiar procedures and are skeptical or hesitant about introducing new methods. In addition, both sides must approach each other.

Technical Challenges
Depending on the required changes in the design of the non-MD, there might be technical challenges in terms of development, implementation, and maintenance. The range spans from software to hardware development and includes EMC, biocompatibility, documentation, labelling, and further issues.

Cost Implications
Non-MD manufacturers must make certain investments in advance, with an uncertain chance of success.

Market Acceptance
Gaining acceptance from the market and establishing the credibility of *MD Comp* can take time. The advantage over existing methods must be proven.

5.2. Mitigation Strategies

To successfully implement the approach *MD Comp*, building trust is crucial. This requires transparent communication about the benefits and functionality.

The involvement of all stakeholders – from end-users and system integrators to regulators – is of high importance to show them how this new approach improves existing regulatory processes without compromising quality or safety. Demonstrators or pilot programs can be helpful to prove the effectiveness and reliability in practice. It is also important to gather feedback and include this feedback into the continuous improvement of the approach.

Further, training, and detailed documentation can also help to promote understanding and acceptance. Success requires that all stakeholders recognize the value of the approach and have confidence in its ability to make conformity assessment more efficient and user-friendly.

5.2.1. Considering Cybersecurity

As measures to ensure a certain level of cybersecurity are increasingly important for a variety of electronic products, EU legislation is evolving during the last years approaching to include more means to provide cybersecurity on hardware and software level. As shown in the present paper, complex medical products may be composed of several components including e.g., computing hardware, sensors and actuators, communication modules and software. Although it is very important that each applied component meets a certain level of cybersecurity requirements intrinsically, the composition of the final medical device demands for a more horizontal consideration of cybersecurity taking into account the interaction of the product's functions and use cases. Thus, the EU is already defining horizontal regulations with the introduction of the Cyber Resilience Act (CRA) [20] that shall be applicable from early 2024 on. The CRA addresses any hardware and software product with digital elements throughout their whole lifecycle. Its conception is based on the classification of products into classes of criticality. In this context, critical products shall undergo special

conformity assessment procedures regarding cybersecurity requirements where non-critical components may have to meet basic requirements only. CRA is pursuing the following goals.

It will:
- ensure that products with digital elements placed on the EU market have fewer vulnerabilities and that manufacturers remain responsible for cybersecurity throughout a product's life cycle,
- improve transparency on security of hardware and software products
- bring benefits to business users and consumers from better protection. [21]

It is planned that manufacturers will have a transition period of 36 months after entry into force to adjust their businesses and get prepared for the CRA requirements.

5.2.2. Integration into the European Regulatory Framework

MDCG
We suggest integrating the *MD Comp*-framework into the European regulatory framework (e.g., MDCG guidance). Such inclusion would imply that the approach is comprehensively assessed and document that it complies with the European regulatory framework, which would strengthen stakeholder confidence. In addition, integration into the European regulatory framework would help to promote a harmonized approach within Member States, improving the efficiency of cross-border business processes and cooperation between countries. Overall, this would be a major step towards a more progressive, consistent, and secure regulatory landscape in Europe.

Definition of Accessory
A revision of the MDR [1]/ IVDR [2] should clearly address the issue of complex IoT-environments containing medical devices and non-medical devices with a focus on criteria to differentiate between accessory and *MD Comp* products which are not regulated within the framework of the MDR [1]/ IVDR [2].

5.2.3. Extending to further Standards / Technical Reports

Table 1 shows as an example the application of the *MD Comp* framework to selected chapters of IEC 60601-1 [15]. In continuation of the considerations presented here, further standards and technical reports must be considered, such as ISO 14971 [16] and ISO/TR 24971 [13]. Though IEC 60601-1 [15] covers Programmable Electrical Medical System (PEMS) in chapter 14, IEC 62304 [18] must be considered, too, in case software is present in the device(s).

In addition, consideration should be given to incorporating the presented approach to standardization work, nationally and internationally.

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A. Examples

In this section, the benefits of *MD Comp* are explained using two examples.

A.1. Example 1: Implementation in a Hospital Setting

The evolving landscape of healthcare technology is marked by a trend towards greater device collaboration and connectivity within hospital environments. It is particularly expected that such systems jointly transmit multimodal parameters to artificial intelligence and similar automated systems, which can fundamentally support the work of clinical personnel. The consolidation and transmission of data are prerequisites for any backend software applications classified as medical devices. Devices responsible for communication are expected to be considered more integral parts of medical products in the future than is currently the case.

This trend includes the widespread use of monitoring systems, body-worn sensors, and a deeply interconnected network of medical devices, aiming to improve patient care and outcomes. The thrust towards this advanced level of integration is driven by the potential of technology to offer more precise, real-time monitoring and personalized care.

A critical aspect of this evolution is the integration of technologies not traditionally classified as medical devices, such as routers and gateways. These devices play a crucial role in establishing robust wireless communication networks within hospitals. However, their use in more sensitive areas, such as operating rooms or intensive care units, is limited due to their non-compliance with medical device standards. This limitation represents a significant missed opportunity, as the enhanced connectivity and data exchange capabilities of these devices could significantly improve operational efficiency and patient care in these critical environments.

The concept of *MD Comp* offers a promising solution to this challenge. By ensuring that devices like routers and gateways meet the additional requirements of medical device regulations from the outset, they can be more easily integrated into the hospital's operational environment. This approach would allow for the use of advanced wireless technologies in more critical areas of the hospital, enhancing the overall capability of the healthcare technology ecosystem.

Especially within hospitals, it can be expected that AI-based assistance systems will support clinical staff in diagnosis and therapy selection. Depending on whether all components involved in data collection and analysis are *MD Comp* compliant, the credibility of the output from such systems could be more easily assessed by clinical personnel.

For instance, consider the integration of Bluetooth Low Energy (BLE) modules in medical devices. Currently, the onus is on medical device manufacturers to ensure that these modules comply with all relevant medical standards, a process that can be time-consuming and costly. Under a *MD Comp* system, these modules would already meet these standards, allowing for quicker and more cost-effective integration into medical devices.

Looking to the future, the implementation of a *MD Comp* system promises to significantly streamline the introduction of innovative technologies into the medical product sector. By reducing the barriers and costs associated with compliance, this system can accelerate the pace of medical innovation, research, and product development. It could lead to a more dynamic and efficient healthcare environment, where the latest technological advancements are more readily available to enhance patient care and operational effectiveness in hospitals.

A.2. Example 2: Remote Monitoring and Data Analytics

It is expected that remote monitoring will increase in the future, as it brings several advantages. By reducing the need for frequent clinic visits, it relieves clinics and enhances patient comfort. Real-time monitoring ensures fast identification of health issues, enabling timely interventions and contributing to enhanced disease management. This approach not only improves patient engagement through active participation but also leads to cost savings by minimizing unnecessary hospital visits.

Moreover, the personalized insights derived from aggregated data support tailored healthcare strategies, fostering a more effective and patient-centric approach. Overall, remote monitoring enhances patient safety, optimizes resource utilization, and marks a transformative step toward more accessible and personalized healthcare.

Most likely, AI-driven support systems will be increasingly used for diagnosis and therapy recommendations. The underlying software for these systems will be medical devices, primarily relying on communication modules between vital sensors and computing units. If all components involved meet certain requirements within an *MD Comp* framework, it can significantly simplify the risk analysis of software-based medical devices.

The risk analysis of multiple involved units is especially simplified when the communication units involved already meet some medical device-related requirements:

- Software on the body-worn sensors, which rely on feedback from the master unit.
- Software on the master unit that orchestrates communication within the WBAN.
- AI Frameworks on a clinic server which combines data or parameters of multiple patients.

In particular, the assessment of the relevance of automated recommendations and diagnoses would be easier assessed if the involved components are *MD Comp*. Especially, such remote monitoring systems could also be used for emergency detection. In addition, patient safety is significantly increased when the involved products are classified as MD Comp, which the manufacturers of communication modules can achieve through a simplified process.

B. Step-by-Step application of the framework

By applying the suggested framework, the non-medical device will fulfill applicable state-of-the-art requirements for medical devices, focusing on safety and security whilst omitting medical-device-specific characteristics. Characteristics related to a specific clinical purpose (because a non-medical device has no clinical purpose) are not included in these considerations. This framework creates a novel category of devices / components, named *MD Comp* Figure 2 shows the application of the *MD Comp* framework.

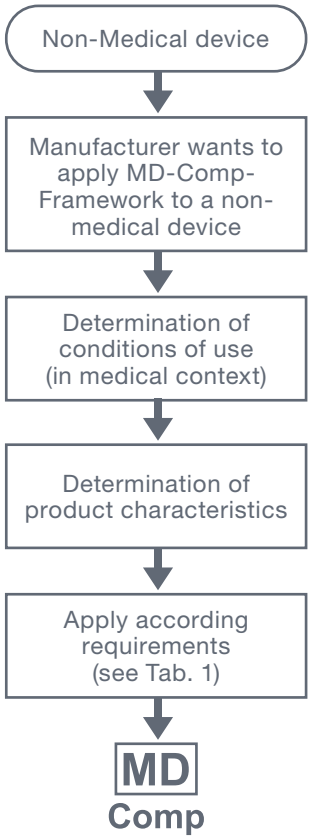

Fig. 2: Step-by-Step approach

This pre-conformity to healthcare standards allows manufacturers and system integrators to concentrate on the unique needs of the system's medical application. The approach simplifies achieving regulatory approval since the component unrelated to medical devices will not cause delays in compliance. Additionally, the label 'MD COMP' could suggest a competitive edge in the market, making these devices/components more likely to be favored for use in medical settings.

Refer to Table 1 (above) for further details.

However, putting the label *MD Comp* on a device/component does not automatically mean that these components can be merged without additional evaluation into a medical system. This is due to the potential implications that might arise from the final configuration.

Acronyms

CRA	Cyber Resilience Act
EMC	Electro-magnetic Compatibility
ETSI	European Telecommunications Standards Institute
EU DoC	EU Declaration of Conformity
GSPR	General Safety and Performance Requirements
IVDR	In Vitro Diagnostic Regulation
MD	Comp Medical Device Compliant
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
NLF	New Legislative Framework
PEMS	Programmable Electrical Medical System
RED	Radio Equipment Directive
UDI	Unique Device Identification

Glossary

Accessory for a medical device is defined in Art. 2 (2) [1] as "an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)".

European Telecommunications Standards Institute European Telecommunications Standards Institute (ETSI) provides members with an open, inclusive, and collaborative environment. This environment supports the timely development, ratification, and testing of globally applicable standards for ICT-enabled systems, applications, and services.

General Safety and Performance Requirements The General Safety and Performance Requirements (GSPR) are defined in Annex I of [1] and describe a set of requirements ensuring the safety and effectiveness of medical devices.

HIPAA Health Insurance Portability and Accountability Act. This 1996 U.S. law governs the security and privacy of protected health information (PHI) and patient access to medical records.

In Vitro Diagnostic Regulation The In Vitro Diagnostic Regulation (IVDR) is a regulatory framework for the European Union that pertains to in vitro diagnostic (IVD) medical devices. This regulation, which replaces the previous In Vitro Diagnostic Directive (IVDD), aims to ensure a high level of safety and performance for IVD devices within the EU market.

Medical Device Coordination Group The Medical Device Coordination Group (Medical Device Coordination Group (MDCG)) deals with key issues from the medical devices sector, from Notified Body oversight or standardization to market surveillance, passing by international matters, new technologies and clinical investigation. Its expertise originates from its division in 13 subgroups, which respectively provide advice and draft guidance on their expertise field. The members of the subgroups are appointed by the Member States for a duration of 3 years. Stakeholders and European based associations participate in the meetings following applications to dedicated calls for expression of interest. They meet regularly with the EU Commission as Chair.

Medical Device Regulation The Medical Device Regulation (MDR) is an EU regulation that governs the safety and performance of medical devices. It sets stricter standards for manufacturing and distribution, improves transparency through more detailed labeling and strengthens post-market surveillance. The MDR replaces the previous Medical Device Directive (MDD) and came into force in May 2017, with a transitional period until May 2021.

PEMS A Programmable Electrical Medical System describes an equipment or a system that contains one (or more) system(s) which are based on one or more central processing units, including software and interfaces. The term is defined in [15], 3.90.

Unique Device Identification Unique Device Identification (UDI) is a unique code assigned to medical devices. This system helps to identify medical devices through their distribution and use.

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