Software Quality and Compliance in Intelligent Health Monitoring Systems: A Case Study of Baby FM

Bojan Gutić[1], Tamara Papić[1] and Pavle Dakić[2,3]

[1]Faculty of Technical Sciences, Singidunum University, Danijelova 32, 11000 Belgrade, Serbia
[2]Faculty of Informatics and Computing, Singidunum University, Danijelova 32, 11000 Belgrade, Serbia
[3]Institute of Informatics, Information Systems and Software Engineering, Faculty of Informatics and Information Technologies, Slovak University of Technology in Bratislava, Ilkovičova 2, 842 16 Bratislava, Slovakia

Abstract

Integrating artificial intelligence (AI) into wearable health monitoring systems introduces both innovation and regulatory complexity, requiring a standardized approach to ensure patient safety, software robustness, and compliance with international medical device regulations. This paper presents a comprehensive case study of Baby FM, an AI-powered wearable medical device developed for continuous temperature monitoring in pediatric and veterinary care. The system combines real-time sensing, secure cloud connectivity, and anomaly detection through interpretable AI models. We detail a structured approach to achieving high software quality through the implementation of a customized Quality Management System (QMS), in compliance with ISO 13485, ISO 14971, and IEC 62304. The QMS supported modular documentation, traceability, risk control, and test automation throughout the product life cycle. In addition, the study outlines the preparation of technical documentation for CE and ALIMS certification, including verification and validation evidence, clinical benefit justification, and post-market surveillance planning. Beyond the internal development and compliance strategy, this paper provides a comparative overview of standard adoption in multiple industries, including the med-tech, pharmaceutical, and industrial IoT sectors. This case study presents several key findings: Modular QMS implementation enabled incremental regulatory compliance without stalling agile software development, Early adoption of ISO 13485, ISO 14971, IEC 62304, and MDR 2017/745 reduced regulatory friction and aligned documentation with development milestones, Embedding explainable AI techniques (SHAP visualization and audit trails) improved transparency, clinician trust, and regulator acceptance. Comparative analysis confirms that medtech devices require more stringent certification than pharma and health IT but deliver stronger post-market accountability. The scalable architecture supports future extensions in oncology, fertility, and livestock monitoring. The findings illustrate how practices from these sectors can inform the development of intelligent health systems and guide strategic decisions for startups seeking certification. Insights from real-world clinical trials, regulatory interactions, and AI transparency strategies offer a replicable methodology for innovators looking to balance agility and compliance in the development of AI-driven medical products.

Keywords

Artificial Intelligence, Software Quality, AI in Healthcare, Wearable Health Monitoring, Risk Management, CE Certification, Baby FM

1. Introduction

In the last decade, advances in wearable technologies have fundamentally reshaped the way health data is collected and analyzed [1]. The convergence of miniaturized medical sensors, mobile applications, and cloud-based platforms has enabled the development of patient monitoring systems that go far beyond isolated measurements. Today's intelligent devices deliver real-time insights, dynamic feedback loops, and adaptive support for clinical decisions. This shift has been especially impactful in areas such as neonatal [2] and veterinary medicine, where even minor fluctuations in physiological signals can precede visible symptoms and require timely intervention.

SQAMIA 2025: Workshop on Software Quality, Analysis, Monitoring, Improvement, and Applications, September 10–12, 2025, Maribor, Slovenia

*Corresponding author.
†These authors contributed equally.
bgutic@singidunum.ac.rs (B. Gutić); tpapic@singidunum.ac.rs (T. Papić); pdakic@singidunum.ac.rs (P. Dakić)
0000-0002-1085-4718 (B. Gutić); 0000-0002-9666-7824 (T. Papić); 0000-0003-3538-6284 (P. Dakić)

The momentum behind wearable medical devices is driven by a combination of technical innovation and systemic transformation in healthcare. Enhanced sensor accuracy, lower power consumption, and user comfort have made continuous measurement feasible outside traditional clinical settings. At the same time, advances in wireless protocols—such as Bluetooth Low Energy (BLE) and Narrowband IoT (NB-IoT)—have made it possible to securely transmit patient data with minimal latency. These capabilities are increasingly aligned with preventive, personalized medicine models, which rely on ongoing monitoring rather than episodic clinical visits [3, 4]. However, as the capabilities of these devices grow, so do the responsibilities of their developers. Manufacturers must ensure not only robust performance, but also security, safety, and conformity with highly regulated development standards.

The Baby FM system was created in response to a distinct clinical need: continuous, non-invasive temperature tracking in infants and small animals, particularly in environments where access to care is limited or periodic checks are insufficient. Baby FM comprises a CE-compliant wearable sensor, a mobile application, and a cloud back-end that enables longitudinal monitoring, predictive alerts, and integration with electronic health records. Unlike traditional thermometers or infrared devices, the system allows for round-the-clock data collection, supports pattern recognition, and offers clinicians traceable, explainable outputs for decision-making.

To navigate the regulatory landscape, the Baby FM team aligned its development approach with the European Medical Device Regulation (EU MDR), under which the device qualifies as a Class IIa product. This classification demands strict technical documentation, software validation, and implementation of a formal Quality Management System (QMS). The process involved compliance with the following standards:

- ISO 13485, which sets out the requirements for QMS specific to medical device manufacturers and emphasizes documentation, traceability, and continuous improvement [5, 6].
- ISO 14971, which defines a structured framework for identifying and mitigating risk throughout the product life cycle [7].
- IEC 62304, which governs the entire life cycle of medical software, from requirements analysis to testing, maintenance, and post-market support [8].

To offer a clearer understanding of how quality and safety standards are applied across different industries, we included a comparative table based on sector-specific usage that can be found in Table 1 in Section 3.

The focus is on standards like ISO 13485, ISO 14971, and IEC 62304, which are foundational in the medical device field. Their implementation is also examined in related sectors such as pharmaceuticals, digital health platforms, and industrial IoT. This comparison sheds light on how regulatory priorities and technical expectations vary across domains, despite sharing similar goals related to reliability, risk mitigation, and system integrity.

Startups like Baby FM often face additional complexity due to limited resources and short development cycles. Yet research has shown that a phased and modular approach to ISO 13485 implementation can be both feasible and effective in early-stage environments [5, 9].

This paper presents a structured case study of how Baby FM was designed, validated, and prepared for certification. We explore the intersection of software quality, risk management, and cross-sectoral standardization. Through this example, we aim to contribute actionable insights for technology developers and medical innovators seeking to navigate the evolving field of intelligent health systems while remaining compliant with national and international regulations.

This paper is structured to lead the audience by way of a logical arrangement of thoughts and findings that are as follows: Section 1 Introduction introduces the integration of AI in wearable medical devices and outlines the objectives and scope of the Baby FM case study. Section 2 Materials and Methods describes the system architecture, development tools, standards applied, and methodological framework used throughout the study. Section 3 Literature Review This section reviews existing work on AI-driven health monitoring, regulatory compliance, and quality management in medtech and related sectors. Section 4 Certification Pathway and Technical File Preparation this section outlines the structured process of preparing technical documentation for CE and ALIMS certification, including risk analysis and verification evidence and details the design and deployment of a modular QMS aligned with ISO 13485, ISO 14971, and IEC 62304 to support development and compliance. Section 5 Results this section presents the outcomes of QMS implementation, certification milestones, and the impact of explainable AI on transparency and acceptance and evaluates the device's clinical accuracy, market comparison, and internal quality metrics. Section 6 Discussion: Lessons Learned and Strategic Trade-offs reflects on the practical challenges, key insights, and strategic decisions involved in balancing agile development with regulatory demands. Section 7 Conclusion this section summarizes the case study's key contributions and offers guidance for startups pursuing certification of AI-powered medical technologies.

2. Materials and Methods

To acquire a thorough knowledge and methodology for the system architecture presented in this document, a structured approach was used to infer links between components based on typical data flow patterns in IoT and healthcare systems.

While clinical evaluation were carried out in partnership with two university-affiliated hospitals in Belgrade: The Pulmonology Clinic and the Institute for Infectious and Tropical Diseases. These studies validated system performance in clinical environments, focusing on accuracy, user comfort, and alert responsiveness. The findings were compiled into a Clinical Evaluation Report (CER), meeting MDR Annex XIV requirements [10].

In our clinical trial, standard hospital gallium thermometer will be used along with our device by applying comparative analysis. Clinical trial methodology was followed by ISO 14155 for planning and execution, while all risk analyses were grounded in ISO 14971. Usability evaluations adhered to IEC 62366-1 [11], addressing interface design, alarm clarity, and minimizing user error. A Summary of Safety and Clinical Performance (SSCP) was also prepared, supporting public transparency for CE-certified devices [12].

As Baby FM incorporates AI features, additional focus was given to documentation of model transparency and traceability of used methodology. Collaboration with an experienced Notified Body led to improvements in explainability of AI logic, training validation, and output interpretation. This was key for meeting MDR Article 61 and Recital 48, which stressed the importance of justifiable and interpretable software behavior [13, 14]. Parts related to the data aspect are further explained in Data Availability Section 7.

3. Literature Review

The past decade has seen a swift advancement in the incorporation of intelligent technologies within healthcare systems, particularly with the increasing presence of AI-powered wearable and implantable medical devices.

These technologies now facilitate various clinical functions, including early detection of diseases and ongoing patient monitoring, particularly in fields such as cardiology, oncology, pediatrics, and post-operative care. Although the potential benefits are widely recognized, these innovations also raise current issues regarding transparency, regulatory control, and integration into clinical practices.

3.1. International standards as basis for the design, validation, and monitoring

To tackle these issues, international standards offer a systematic basis for the design, validation, and monitoring of products after they enter the market. ISO 13485 [6] provides a framework for creating and sustaining a Quality Management System (QMS) tailored to medical devices, emphasizing decision-making based on risk and comprehensive documentation throughout the lifecycle. ISO 14971 [7] enhances this by outlining approaches for recognizing, assessing, and managing risks at every phase of a product's existence. In the realm of software, IEC 62304 [8] outlines the requirements for development, verification, and ongoing maintenance in applications where safety is critical, necessitating organized software classification and traceability matrices.

3.2. Software Engineering Considerations for AI-Powered Wearables

Wilmink et al. [15] demonstrated that the combination of wearable devices and AI-driven digital health platforms can lead to better health management in assisted living communities, emphasizing the potential for these technologies to support aging populations.

Similarly, Porbundarwala et al. [16] reported positive health outcomes and increased user trust in AI-driven health monitoring, underscoring the transformative impact of personalized health insights provided by such devices. Furthermore, Alzghaibi [17] identified key factors influencing adoption, including user education and trust, which are critical for integrating AI wearables into chronic disease management.

3.3. Quality and safety standards

To provide a better understanding of how quality and safety standards are implemented across various industries, a comparative analysis has been incorporated on the following Table 1.

Table 1
Cross-Industry Adoption of Medical and Health Standards. Source: author's contributions.

Standard	Medical Devices	Health IT	Pharma	Industrial IoT
ISO 13485	High	Medium	Medium	Low
ISO 14971	High	Low	Medium	Low
IEC 62304	High	Medium	Low	Medium
ISO/IEC 27001	Medium	High	Medium	High
ISO 10993-1	High	Low	High	Low
MDR 2017/745	High	Medium	Medium	Low

It illustrates that, although ISO 13485, ISO 14971, and IEC 62304 are well-established in the medical device industry, other sectors such as pharmaceuticals, health IT, and industrial IoT focus on different elements like cybersecurity (ISO/IEC 27001) or data integrity. This diversity highlights the distinctive regulatory objectives and risk profiles of each sector.

The growing interconnection of AI technologies across various sectors has led both regulators and researchers to reevaluate how healthcare software is classified. A significant development in this area is the European Union's Artificial Intelligence Act, which sets forth new requirements for AI systems based on their purpose and associated risk levels. In the realm of healthcare, in regard to European Union Artificial Intelligence Act for Healthcare [18] software is now divided into three primary categories:

1. AI systems that are integrated into a certified medical device
2. Supplementary or companion software that aids a medical device without being essential to its operation
3. Independent software that executes a medical function on its own, identified as Software as a Medical Device (SaMD)

Each of these categories necessitates a specific approach to compliance. Embedded systems need to comply with both the Medical Device Regulation (MDR) and IEC 62304, ensuring traceability throughout their lifecycle and adherence to device-level safety measures. Support software is often required to meet GDPR and ISO/IEC 27001 standards, particularly when it deals with sensitive health information, and must demonstrate usability and risk management through ISO/IEC 62366 and ISO/IEC 25010.

Software as a Medical Device (SaMD) faces the most rigorous regulatory oversight under the AI Act because of its ability to make autonomous decisions. It must be clearly transparent, auditable, explainable, and clinically validated prior to its implementation.

The policy report by AIHTA [19] highlights the necessity for harmonization of standards, particularly in relation to post-market monitoring of adaptive AI systems. Additionally, emerging frameworks increasingly promote continuous oversight, version management, and impact evaluation for any AI model linked to or integrated with a regulated medical function.

4. Certification Pathway and Technical File Preparation

The classification of Baby FM under the European Union Medical Device Regulation (EU MDR) 2017/745 was based on the device's intended use for continuous temperature monitoring and its potential diagnostic impact. As outlined in Rule 10 of Annex VIII [20], Baby FM falls under Class IIa, since it monitors physiological parameters that may influence clinical decisions. This categorization requires comprehensive regulatory engagement, including conformity assessment by a Notified Body, documented clinical evaluation, and a structured post-market surveillance framework.

During the early stages of development, the Baby FM team mapped out its regulatory strategy to ensure full alignment with the General Safety and Performance Requirements (GSPRs) defined in Annex I of the MDR. A detailed checklist was developed to collect and track all compliance-related evidence, laying the groundwork for the Technical Documentation needed for CE marking and domestic market authorization via Serbia's national regulatory body, ALIMS.

The technical documentation was compiled by MDR Annexes II [21] and III [22], and it included:

- Formal description of the intended use, patient group, and clinical value
- Risk documentation consistent with ISO 14971, covering usability and risk mitigation
- Comprehensive software design overview, supported by cybersecurity threat modeling
- Verification and validation records linked to specific system requirements
- Full labeling, packaging, and Instructions for Use (IFU) tailored to clinical and home users

All documentation was structured using the IMDRF Table of Contents (ToC) model to support international regulatory compatibility. The Device Master Record (DMR) included the Bill of Materials (BoM), design schematics, source code summaries, and a documented update history. Cybersecurity was treated as a key area, incorporating encryption protocols, firmware protection mechanisms, and access control strategies in line with MDCG 2019-16 recommendations [23].

Supplementary documentation included:

- A Software Bill of Materials (SBOM) covering all third-party and open-source components according to NTIA [24]
- A Data Protection Impact Assessment (DPIA) aligned with GDPR Article 35 [25]
- Clinical testing results and caregiver interaction mapping in regard to FDA [26]
- Supplier audits and visual documentation of the manufacturing process according to ISO 13485 [6]

Baby FM's software outputs were supported by clinician-facing dashboards displaying decision pathways, confidence scoring, and input-output relationships. Training routines were maintained with reproducibility audits and version tracking. Software updates followed a defined validation and deployment protocol consistent with IEC 82304-1 standards [27] for medical-grade software life cycle management.

This rigorous documentation effort resulted in a fully compliant technical file, enabling Baby FM to achieve both CE certification and national approval in Serbia. The approach demonstrates how structured regulatory planning, proactive documentation, and multidisciplinary collaboration can help startups achieve compliance in complex health technology markets.

4.1. Quality Management System

Implementing a Quality Management System (QMS) was an essential measure for aligning Baby FM with medical device regulations and ensuring traceability throughout the development process. From the beginning, the team chose ISO 13485:2016 [6] as the primary framework to support their compliance initiatives.

Recognizing the distinct challenges that early-stage startups encounter, the QMS was crafted to be both flexible and modular. This strategy enabled the team to progressively fulfill necessary regulatory milestones while still adhering to an agile, iterative development approach.

Central to Baby FM QMS was a comprehensive set of documentation, including:

- Design and Development Plan (DDP)
- Software Requirements Specifications (SRS)
- Architecture and Modular Breakdown Document
- Verification and Validation Plan (VVP)
- Design History File (DHF)
- Device Master Record (DMR)
- Software Traceability Matrix and Risk Assessment Files

Every one of these artifacts was designed with traceability and readiness for audits in mind. The V-model was utilized to structure development stages, incorporating specific checkpoints that connect design inputs with verification results.

Baby FM closely followed the framework specified in IEC 62304 [8] for software validation, which requires a software lifecycle process that includes planning, requirements analysis, architectural design, implementation, testing, release, and maintenance.

Risk analysis was performed in accordance with ISO 14971 [7], identifying software-specific hazards and mapping out control measures. A Risk Analysis Table (RAT), created and updated to meet ALIMS and EU MDR standards, outlined mitigation strategies, potential risks, severity ratings, and thresholds for risk acceptability. Examples of risks included the loss of data integrity from BLE disconnections, incorrect temperature thresholds resulting in false negatives, or delays in clinical alerts due to cloud service downtime. Each risk was thoroughly documented with a unique identifier, source traceability, and connections to relevant mitigation procedures.

Automated unit and integration testing were implemented to aid regression cycles, with coverage metrics monitored via CI/CD pipelines [28, 29, 30]. End-to-end system testing encompassed realistic usage scenarios that featured simulated fever conditions, hardware malfunctions, and user mistakes. These tests were validated against expected system behavior and recorded in the Software Verification Report (SVR). Test evidence was directly linked to requirement identifiers, ensuring traceability was maintained.

5. Results

In the following sections, we give the findings from the analysis of the system architecture described in the document. These findings demonstrate the structured interactions and data flows inside the B2C and B2B frameworks, as well as the administrative monitoring capabilities.

Model used in this case is gradient-boosted decision trees applied with XGBoost. Data is from the de-identified 15 pulmonology patients from the pilot study. Model evaluation involves main performance metrics on both training and validation datasets, including accuracy, precision, recall, F1 score, and AUC.

The UML class diagram efficiently depicts the relationships between essential components. This is emphasizing their responsibilities and connectedness in producing a cohesive solution. This results introduction prepares the groundwork for a thorough examination of the system's functionality and performance, providing insights into its operational efficiency and scalability.

5.1. System Architecture and AI components for Baby FM

The Baby FM platform is a comprehensive health monitoring system aimed at facilitating high-frequency, non-invasive temperature monitoring for both pediatric and animal patients. Its design highlights the integration of biomedical sensor technology, secure mobile communication, and cloud-based artificial intelligence analytics.

The system architecture is presented on the Figure 1 and comprises three interrelated components:

1. Compact wearable sensor
2. Mobile application serving as a gateway and user interface
3. Cloud-hosted AI engine along with a data repository

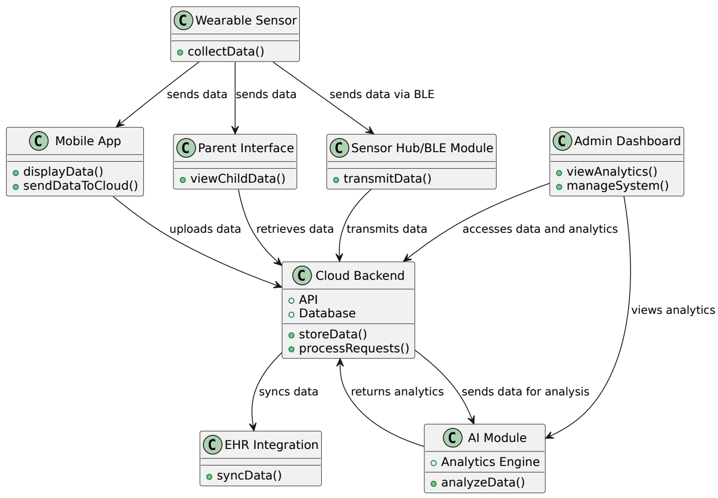

Figure 1: BabyFM System Architecture Classes - B2C & B2B . Source: author's contribution.

The sensor module features a high-accuracy temperature sensor that meets ISO 80601-2-56 standards and is designed to measure core-equivalent skin temperature from one-second intervals with 0.1% accuracy. It utilizes Bluetooth Low Energy (BLE) for wireless communication, ensuring low power usage, which makes it ideal for overnight monitoring in both home and clinical settings. The casing of the sensor is biocompatible and safe for skin contact, while the firmware is equipped with self-check mechanisms and fallback error conditions in line with IEC 60601-1 electrical safety standards.

The application is intended for both healthcare professionals and caregivers. It shows real-time readings, trend charts, and alert notifications triggered by AI-detected anomalies. The application utilizes on-device encryption with AES-128 before sending any data. Additionally, it incorporates anonymization procedures and consent workflows that comply with GDPR standards. Clinical setups facilitate the integration with Electronic Health Records (EHRs) via a secure RESTful API and modules compatible with HL7 FHIR [31].

The AI component operating on the backend utilizes a cloud infrastructure to interpret temperature patterns in real time. The system for detecting anomalies combines supervised learning, which involves clinician-validated labels, with unsupervised clustering methods to differentiate between normal variations and significant medical deviations. A key aspect of this system is its interpretability layer, which depicts the AI's decision-making process through SHAP (SHapley Additive exPlanations) values and audit logs. This not only enhances clinical confidence but also meets regulatory requirements for transparency in AI systems, as specified in the EU AI Act [32].

5.2. Clinical Accuracy

As illustrated in Figure 2, quantitative findings from a controlled clinical study conducted under ethical approval comparing Baby FM with a gallium thermometer, Baby FM achieved ±0.1°C accuracy in 91.2% of the cases.

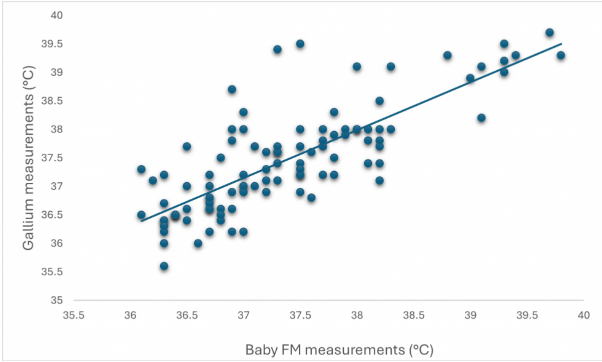

Figure 2: Comparison of temperature readings between Baby FM and gallium thermometers in a clinical study (N=42). Source: author's contribution.

5.3. Market Comparison and limits of the study

We have incorporated clinical carer feedback gathered during pilot trials in clinical settings at hospitals affiliated with the University, even though formal veterinary usability studies are still in progress and will be part of future work. The main concerns raised by the feedback were automated alert trust, comfort during night time monitoring, and ease of use. Due to Baby FM's continuous and non-invasive measurement, more than 80% of participating carers preferred it over conventional oral or axillary methods, according to the overwhelmingly positive informal feedback.

In Table 2, we can see the comparison between Baby FM to industry-leading commercial temperature monitoring systems like TempTraq®.

Table 2
Comparison of Baby FM with other wearable thermometers. Source: author's contributions.

Feature	Baby FM	TempTraq	Medtronic Vital Sync
Accuracy	±0.1°C	±0.3°C	±0.2°C
Continuous Monitoring	Yes	Yes (72h only)	Yes
CE Marked	Yes (Class IIa)	No	Yes
Data Integration	HL7 / FHIR	Email export	Hospital-only
Pediatric Usability	Tailored	Generic	No

5.4. Internal Quality Metrics

- Unit test coverage: 94%
- Requirement-test traceability: 100%
- Avg. change request resolution: 2.5 days
- Monthly risk review updates since Q3 2024

These metrics help quantify our QMS efficiency and demonstrate adherence to continuous quality monitoring protocols.

6. Discussion: Lessons Learned and Strategic Trade-offs

The development of Baby FM, an AI-powered medical device for continuous body temperature monitoring, reveals a set of important insights for health technology innovators working in highly regulated environments. This case exemplifies how early integration of regulatory principles, quality assurance standards, and clinical usability requirements can serve not only as compliance measures but also as drivers of product maturity and stakeholder trust. The Baby FM team faced a number of significant obstacles throughout the development and certification process:

- To integrate DevOps pipelines with ISO 13485 requirements, formal branching, tagging, and audit mechanisms must be established within CI/CD workflows.
- AI transparency: Designing visualisations (SHAP plots, confidence scores) to reveal model logic was necessary to ensure clinical interpretability.
- Risk analysis: It was necessary to map cloud delays, BLE dropouts, and false temperature alerts into risk tables that complied with ISO 14971.
- Documentation control: Git-based QMS tools and digital signatures were used to manage document versioning and traceability because internal staffing was limited.

6.1. Navigating AI Transparency and Clinical Interpretability

Integrating artificial intelligence into a medical device adds a distinct layer of complexity. It is not sufficient for the algorithm to perform accurately—regulators and clinicians alike now expect transparency, traceability, and explainability. In response to this, the Baby FM development included built-in interpretability tools that translated model behavior into clear clinical signals. Visualization dashboards were used to display input-output relationships, anomaly confidence scores, and historical signal context. This approach addressed concerns outlined in the MDR [21, 22, 14] and anticipated future requirements from the EU AI Act [32], providing both auditors and users with meaningful insights into the algorithm's decision process.

6.2. Regulatory Planning as an Ongoing Process

Instead of viewing compliance as a final step, regulatory planning was integrated into every development phase. The team utilized the General Safety and Performance Requirements (GSPRs) from the outset as a guide for aligning design activities, verification tests, and risk evaluations. The technical documentation was developed according to MDR Annexes II and III, while the use of the IMDRF Table of Contents ensured compatibility with international submission formats. Clinical validation efforts were grounded in ISO 14155 and ISO 14971, ensuring a continuous connection between pre-market data and post-market expectations.

6.3. Embedding Cybersecurity and Data Protection from the Start

Given the nature of Baby FM as a connected device handling personal health data, cybersecurity and privacy were not treated as add-ons but as design imperatives. The system architecture incorporated AES-128 encryption, device-level authentication, and GDPR-compliant anonymization policies from the prototyping stage. These elements aligned with ISO/IEC 27001 [33] and MDCG cybersecurity recommendations and played a critical role in building user trust, especially in clinical settings dealing with vulnerable pediatric populations.

6.4. Sector Comparison and Regulatory Depth

Compared to other segments of the health technology field, such as pharmaceutical software tools or digital health services, the path to compliance for medical devices is significantly more demanding. These devices are expected to meet strict, layered requirements that span from initial design to long-term use in clinical environments. While some industries can apply quality and safety standards selectively, medical device developers must demonstrate full regulatory alignment across engineering, software safety, and patient risk management.

As illustrated in Figure 3, medtech remains the most consistent adopter of standards like ISO 13485, ISO 14971, and IEC 62304, reflecting a high level of traceability, system validation, and readiness for global approval pathways.

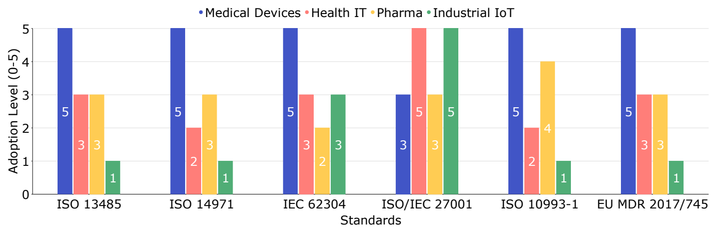

Figure 3: Cross-Sector Adoption of Quality and Risk Standards. Source: author's contribution.

6.5. Strategic Outcomes and Future Outlook

The Baby FM experience confirms that small teams, even with limited resources, can navigate complex certification pathways when compliance is built into the product strategy—not retrofitted. The decision to invest early in quality systems, regulatory intelligence, and human-centered design significantly reduced rework and accelerated engagement with clinical partners and regulatory reviewers. As the company moves toward broader applications (e.g., oncology, fertility, veterinary use), the scalable foundation established through these strategies will support both AI life cycle governance and regulatory expansion.

7. Conclusion

The development of Baby FM illustrates how startups in digital health can successfully navigate regulatory and technical challenges by planning for compliance from the earliest stages.

Instead of separating quality assurance from design, the team adopted a unified development model that made safety, traceability, and documentation a natural part of the engineering workflow. In terms of technical performance, Baby FM achieved a temperature measurement accuracy of ±0.1°C, with a fever detection precision of 91.2% with the data extracted from the ongoing registered clinical study.

Baby FM shows that responsible development - grounded in standards, focused on usability, and aligned with regulatory logic - can help emerging health technologies succeed even in complex environments.

By relying on established international standards, the team was able to build a device that met both clinical and regulatory expectations. This foundation made certification processes more efficient and helped reduce delays during validation and review. Collaboration with medical professionals during early testing also ensured that the system addressed real clinical needs.

One of the system's distinctive features is its use of interpretable artificial intelligence. Rather than relying on opaque algorithms, Baby FM provides clear logic paths and visual tools that help users understand how and why the device issues alerts. This transparency played an important role in the building of trust between healthcare professionals and regulatory reviewers.

Looking to the future, the core technology behind Baby FM is being extended to support new use cases. These include temperature monitoring in oncology patients, integration with reproductive health tools, and applications in animal care. Due to its modular structure, the system can be adapted to each setting with minimal redesign, allowing faster rollout and easier validation.

The company is also building a cloud-based service to connect its devices to hospital infrastructure. Using established data exchange protocols, this platform will enable health institutions to incorporate Baby FM into existing workflows, expanding its value as both a device and a data tool.

This case highlights the importance of integrating quality thinking into innovation, especially in AI-driven medical systems. As regulation becomes more demanding, particularly in areas involving machine learning, the ability to document and explain system behavior will be key to clinical acceptance and international growth.

In further projects, Baby FM will further integrate software engineering, cloud-based AI, secure mobile infrastructure, and biological sensing. Quality management systems will be in line with these procedures. The platform will then be layered with architecture that ensures clinical safety, durability, and regulatory compliance—demonstrating how software innovation for medical devices can be both agile and compliant.

Data availability

In compliance with GDPR Articles 5 and 35, all patient data utilized in the creation and assessment of Baby FM was anonymized. Temperature information is encrypted and saved locally on the user's mobile device when used at home. In clinical settings, information is sent to a hospital-controlled server via secure channels for a de-identified assessment of comfort, safety, and effectiveness. Ethical Committee of the Republic of Serbia granted ethics approval, and all clinical trials collected informed consent. Due to patient confidentiality and regulatory compliance, data are not made publicly available; however, synthetic datasets for research purposes may be made available upon request.

Acknowledgments

We thank Idvorski Laboratory for supporting EMC testing under IEC 60601-1 and Axiom International for providing preliminary precision reports showing 0.1°C accuracy. Clinical Trial data is being collected under NCT06447337 (https://clinicaltrials.gov/study/NCT06447337)

Declaration on Generative AI

The author(s) have not employed any Generative AI tools.

References

[1] A. Mitek, D. Jones, A. Newell, S. Vitale, Wearable devices in veterinary health care, Veterinary Clinics of North America: Small Animal Practice 52 (2022) 1087–1098. doi:10.1016/j.cvsm.2022.05.001.

[2] H. Chen, M. Xue, Z. Mei, S. Bambang Oetomo, W. Chen, A review of wearable sensor systems for monitoring body movements of neonates, Sensors 16 (2016) 2134. doi:10.3390/s16122134.

[3] X. Zhao, R. Tanaka, A. S. Mandour, K. Shimada, L. Hamabe, Remote vital sensing in clinical veterinary medicine: A comprehensive review of recent advances, accomplishments, challenges, and future perspectives, Animals 15 (2025) 1033. doi:10.3390/ani15071033.

[4] L. Lu, J. Zhang, Y. Xie, F. Gao, S. Xu, X. Wu, Z. Ye, Wearable health devices in health care: Narrative systematic review, JMIR mHealth and uHealth 8 (2020) e18907. doi:10.2196/18907.

[5] N. Gasche, Mastering ISO 13485 certification as an agile medical start-up — medium.com, 2021. URL: https://medium.com/biome-diagnostics/mastering-iso-13485-certification-as-an-agile-medical-start-up-dbe6215253cf.

[6] ISO, ISO 13485:2016 — iso.org, 2016. URL: https://www.iso.org/standard/59752.html.

[7] ISO, ISO 14971:2019 — iso.org, 2019. URL: https://www.iso.org/standard/72704.html.

[8] ISO, IEC 62304:2006 — iso.org, 2006. URL: https://www.iso.org/standard/38421.html.

[9] M. F. Lie, M. Sánchez-Gordón, R. Colomo-Palacios, Devops in an iso 13485 regulated environment: A multivocal literature review, in: Proceedings of the 14th ACM / IEEE International Symposium on Empirical Software Engineering and Measurement (ESEM), ESEM '20, ACM, 2020, pp. 1–11. doi:10.1145/3382494.3410679.

[10] MassimoP, ANNEX XIV - Medical Device Regulation — medical-device-regulation.eu, 2019. URL: https://www.medical-device-regulation.eu/2019/08/14/annex-xiv/.

[11] ISO, IEC 62366-1:2015 — iso.org, 2015. URL: https://www.iso.org/standard/63179.html.

[12] MDCG, Summary of safety and clinical performance A guide for manufacturers and notified bodies, 2022. URL: https://health.ec.europa.eu/document/download/5f082b2f-8d51-495c-9ab9-985a9f39ece4_en.

[13] B. Corcoran, EU MDR Article 61 Clinical Evaluation – MED Institute — medinstitute.com, 2024. URL: https://medinstitute.com/blog/eu-mdr-article-61-clinical-evaluation/.

[14] MDR, Recitals 41 - 50 of the EU Medical Devices Regulation (MDR) — de-mdr-ivdr.tuvsud.com, 2021. URL: https://de-mdr-ivdr.tuvsud.com/Recitals-41-50.html.

[15] G. Wilmink, K. Dupey, S. Alkire, J. Grote, G. Zobel, H. M. Fillit, S. Movva, Artificial intelligence–powered digital health platform and wearable devices improve outcomes for older adults in assisted living communities: Pilot intervention study, JMIR Aging 3 (2020) e19554. doi:10.2196/19554.

[16] T. Porbundarwala, S. Lalji, H. Patil, J. Dongardive, Impact of ai in personalised health monitoring using wearable devices, International Journal For Multidisciplinary Research 5 (2023). doi:10.36948/ijfmr.2023.v05i05.7144.

[17] H. Alzghaibi, Adoption barriers and facilitators of wearable health devices with ai integration: a patient-centred perspective, Frontiers in Medicine 12 (2025). doi:10.3389/fmed.2025.1557054.

[18] F. Busch, J. N. Kather, C. Johner, M. Moser, D. Truhn, L. C. Adams, K. K. Bressem, Navigating the european union artificial intelligence act for healthcare, npj Digital Medicine 7 (2024). doi:10.1038/s41746-024-01213-6.

[19] AIHTA, Artificial Intelligence in Health Care with a Focus on Hospitals: Methodological Considerations for Health Technology Assessment, 2024. URL: https://eprints.aihta.at/1546/1/HTA-Projektbericht_Nr.164.pdf.

[20] MassimoP, ANNEX VIII - Medical Device Regulation — medical-device-regulation.eu, 2019. URL: https://www.medical-device-regulation.eu/2019/08/08/annex-viii/.

[21] MDR, Annex II (MDR): Technical documentation — de-mdr-ivdr.tuvsud.com, 2004. URL: https://de-mdr-ivdr.tuvsud.com/Annex-II-Technical-documentation.html.

[22] MDR, Annex III (MDR): Technical documentation on post-market surveillance — de-mdr-ivdr.tuvsud.com, https://de-mdr-ivdr.tuvsud.com/Annex-III-Technical-documentation.html, 2004. URL: https://de-mdr-ivdr.tuvsud.com/Annex-III-Technical-documentation.html.

[23] MDCG, Guidance on Cybersecurity for medical devices, 2020. URL: https://health.ec.europa.eu/system/files/2022-01/md_cybersecurity_en.pdf.

[24] NTIA, ntia.gov, 2021. URL: https://www.ntia.gov/sites/default/files/publications/sbom_related_efforts_oct2021_0.pdf.

[25] GDPR, Art. 35 GDPR – Data protection impact assessment - General Data Protection Regulation (GDPR) — gdpr-info.eu, 2016. URL: https://gdpr-info.eu/art-35-gdpr/.

[26] FDA, Applying human factors and usability engineering to medical devices, 2016. URL: https://www.fda.gov/media/80481/download.

[27] ISO, IEC 82304-1:2016 — iso.org, 2016. URL: https://www.iso.org/standard/59543.html.

[28] P. Dakić, Software compliance in various industries using ci/cd, dynamic microservices, and containers, Open Computer Science 14 (2024). doi:10.1515/comp-2024-0013.

[29] F. Cák, P. Dakić, Creating Feature Model for YAML Generator in CI/CD Pipelines with React Web Application, Springer Nature Singapore, 2024, pp. 529–539. doi:10.1007/978-981-97-3305-7_42.

[30] P. Dakić, Importance of knowledge management for ci/cd and security in autonomous vehicles systems, JITA - Journal of Information Technology and Applications (Banja Luka) - APEIRON 24 (2024). doi:10.7251/jit2401007d.

[31] R. Saripalle, C. Runyan, M. Russell, Using hl7 fhir to achieve interoperability in patient health record, Journal of Biomedical Informatics 94 (2019) 103188. doi:10.1016/j.jbi.2019.103188.

[32] EU, EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act — artificialintelligenceact.eu, 2024. URL: https://artificialintelligenceact.eu/.

[33] ISO, ISO/IEC 27001:2022 — iso.org, 2022. URL: https://www.iso.org/standard/27001.