Research Horizon

ISSN: 2808-0696 (p), 2807-9531 (e)

Research Horizon
Volume: 06
Issue: 04
Year: 2026
Page: 1979-1988

Citation:
Rakhmatullah, M. Y., & Ismail, Y. C. T. (2026). Legal liability of medical device business actors towards patient safety in health services. *Research Horizon*, *6*(4), 1979-1988.

Article History:
Received: July 25, 2026
Revised: August 19, 2026
Accepted: August 22, 2026
Online since: August 25, 2026

Legal Liability of Medical Device Business Actors Towards Patient Safety in Health Services

Mohammad Yusuf Rakhmatullah[1*], Yana Chaeru Taufik Ismail[1]

[1] Department of Law, Faculty of Law, Universitas Islam Nusantara, Bandung, Indonesia

[*] *Corresponding author: Mohammad Yusuf Rakhmatullah (myrakhmatullah@gmail.com)*

Abstract

Medical devices are an essential component of modern healthcare that directly impact patient safety. The increasing use of medical devices in healthcare facilities in Indonesia raises legal issues regarding the liability of business actors when patients suffer losses due to defective or malfunctioning medical devices. This study aims to analyze the legal liability of medical device business actors for patient safety based on the applicable laws and regulations in Indonesia, as well as to identify obstacles and efforts in law enforcement. This study uses a normative juridical approach with a statute approach and a conceptual approach. The findings show that the legal liability of medical device business actors encompasses fault-based liability, strict liability, and product liability under Law Number 8 of 1999 concerning Consumer Protection, Law Number 17 of 2023 concerning Health, and Government Regulation Number 28 of 2024 concerning the Implementation of Law Number 17 of 2023 concerning Health. Law enforcement remains constrained by weak post-market surveillance, limited incident reporting, insufficient supervisory resources, complex distribution chains, technological developments, and low legal awareness among business actors. Strengthening integrated materiovigilance, supervisory capacity, responsive regulations, and regulatory education is necessary to ensure effective patient safety protection.

Keywords

Business Actors, Consumer Protection, Legal Liability, Medical Devices, Patient Safety.

1. Introduction

Quality and safe health services are basic rights guaranteed by the 1945 Constitution of the Republic of Indonesia, particularly Article 28H paragraph (1), which recognizes everyone's right to receive health services (Muhtar et al., 2023; Rayyan et al., 2025). To realize optimal health services, medical devices are an inseparable component of modern medical practice and healthcare delivery. These devices support the diagnosis, prevention, monitoring, and treatment of diseases and medical conditions. Data from the Ministry of Health of the Republic of Indonesia indicate that demand for medical devices in Indonesia continues to rise alongside the growth of healthcare facilities and public awareness of quality health services. Indonesia's medical device market is projected to grow significantly, with annual market value reaching billions of US dollars (Pratono & Ratih, 2019; Prawira & Qolbi, 2025). This growth is driven by demographic changes, urbanization, the increasing prevalence of non-communicable diseases, and the National Health Insurance (*Jaminan Kesehatan Nasional*/JKN) policy, which has expanded public access to healthcare services (Sari & Fikri, 2025).

However, the increase in the use of medical devices also poses risks to patient safety. Various incidents related to medical devices have been reported globally and in Indonesia, including device malfunctions, design defects, production defects, material contamination, and errors in labeling or instructions for use. The World Health Organization (WHO) noted that incidents related to medical devices are one of the main causes of unexpected events (*Kejadian Tidak Diharapkan*/KTD) in health care facilities (WHO, 2003). The International Medical Device Regulators Forum (IMDRF) (2022) reported that medical device recalls have increased consistently in the last decade (Sun et al., 2021).

In Indonesia, the Food and Drug Supervisory Agency (*Badan Pengawas Obat dan Makanan*/BPOM), together with the Ministry of Health, has supervised the circulation of medical devices. However, medical devices are still found in circulation without a distribution permit, that do not meet quality standards, or that have expired. Cases such as the use of defective medical implants, ventilators that did not function optimally during the COVID-19 pandemic, and the circulation of fake diagnostic test kits show that the safety issue of medical devices remains a critical issue that requires serious legal attention (Nadapdap et al., 2022).

Medical device business actors, including manufacturers, importers, and distributors, have a legal obligation to ensure that medical device products they produce, import, or distribute meet quality, safety, and utility requirements. This obligation is regulated in various laws and regulations, including Law Number 8 of 1999 concerning Consumer Protection (Consumer Protection Law), Law Number 17 of 2023 concerning Health (Health Law), and its implementing regulations, including Government Regulation Number 28 of 2024 concerning the Implementation of Law Number 17 of 2023 concerning Health, which contains provisions regarding medical devices (Yannassandi & Kongres, 2023).

Although a regulatory framework has been available, the implementation of law enforcement against medical device business actors who violate the provisions still faces various challenges. Problems include weak post-market surveillance supervision mechanisms, limited supervisory resources, lack of awareness of business actors on regulatory compliance, and low level of incident reporting by health care facilities (Badnjević et al., 2022; Giragn et al., 2025). In addition, the development of increasingly complex medical device technology, including the emergence of software as a medical device and artificial intelligence-based medical devices, poses new challenges in determining legal liability (Manurung et al., 2024; Rayyan & Siregar, 2025).

Based on this description, the issue of legal responsibility of medical device business actors for patient safety is a relevant and important topic to be studied in depth. This study aims to analyze the legal framework governing the responsibilities of medical device business actors for patient safety in health services in Indonesia, identify the applicable forms of legal responsibility for ensuring patient safety, and examine enforcement obstacles while formulating efforts to strengthen legal protection for patient safety. This research contributes by analyzing applicable legal responsibilities, identifying enforcement obstacles, and formulating measures to strengthen legal protection for patient safety.

2. Methods

This research uses the normative legal research method (normative juridical), which is legal research conducted by reviewing and analyzing written legal materials in the form of laws and regulations, court decisions, and legal literature related to the problem being studied. Normative legal research focuses on positive legal norms contained in laws and regulations and examines them systematically to find the truth based on legal scientific logic (Hosnah, 2021).

The research approach used includes two main approaches. First, the statute approach, which involves examining all laws and regulations related to the legal issues being studied, including laws, government regulations, ministerial regulations, and other technical regulations governing medical devices, consumer protection, and patient safety. Second, the conceptual approach, which examines relevant legal concepts such as legal liability, product liability, strict liability, patient safety, and consumer protection in the health sector.

The sources of legal materials in this study consist of primary and secondary legal materials. Primary legal materials include: the Constitution of the Republic of Indonesia of 1945, the Civil Code, Law Number 8 of 1999 concerning Consumer Protection, Law Number 17 of 2023 concerning Health, Government Regulation Number 28 of 2024 concerning the Implementation of Law Number 17 of 2023 concerning Health, Regulation of the Minister of Health Number 62 of 2017 concerning Marketing Authorization of Medical Devices, In Vitro Diagnostic Medical Devices, and Household Health Supplies, Regulation of the Minister of Health Number 4 of 2018 concerning Hospital Obligations and Patient Obligations, and other relevant technical regulations.

Secondary legal materials include law books, scientific journals, research results, dissertations, and academic publications relevant to the research topic. The legal materials were collected through library research by inventorying, classifying, and systematizing them. The legal materials were analyzed qualitatively through legal interpretation, including grammatical, systematic, and teleological interpretation. The analysis compared applicable legal norms with relevant legal doctrines and concepts. The results were then presented descriptively and systematically to formulate conclusions and provide legal arguments regarding the issues examined.

3. Results and Discussion

3.1. Legal Framework for Medical Devices in Indonesia

The legal regulation of medical devices in Indonesia has evolved significantly over the past decade. With the enactment of Law Number 17 of 2023 concerning Health as a replacement for Law Number 36 of 2009 concerning Health, the legal framework in the health sector has undergone a comprehensive update through the omnibus law approach, which consolidates various sectoral provisions into a single law. Article 1 Number 13 of the Health Law defines medical devices as instruments, apparatus, machines, and/or implants that do not contain drugs and are used to prevent, diagnose, cure, and alleviate diseases, treat sick people, restore health in

humans, and/or form structures and improve bodily functions (Purwodono et al., 2025).

The classification of medical devices based on their level of risk is divided into four classes, namely Class A (low risk), Class B (low-to-medium risk), Class C (medium-to-high risk), and Class D (high risk). This classification refers to international standards established by the Global Harmonization Task Force (GHTF) and adopted through the ASEAN Medical Device Directive (AMDD) (Kusumawati et al., 2025; Habilillah & Alfath, 2026). The higher the risk class, the stricter the requirements that business actors must fulfil to obtain a distribution permit.

Government Regulation Number 28 of 2024 concerning the Implementation of Law Number 17 of 2023 concerning Health, as an implementing regulation of the Health Law, regulates in greater detail the production, importation, distribution, and supervision of medical devices. This regulation requires medical device business actors to meet licensing requirements before distributing their products. The licensing process includes the assessment of the safety, quality, and usefulness of products through technical evaluation and conformity assessment. In addition, business actors must implement a quality management system in accordance with applicable standards, particularly ISO 13485 for medical device quality management systems (Bruyndonckx et al., 2020; Sahidu et al., 2023; Risman et al., 2024).

In the ASEAN context, Indonesia also participates in the implementation of the AMDD, which aims to harmonize medical device regulations within the region. This harmonization includes classification standards, conformity assessment requirements, and post-market surveillance systems. The implementation of the AMDD has implications for medical device business actors in Indonesia, requiring them to comply with more harmonized regional standards (Hidayati et al., 2021). Based on these regulatory developments, the regulation of medical devices in Indonesia demonstrates a comprehensive legal framework covering product classification, licensing, quality assurance, conformity assessment, distribution, and post-market surveillance. These provisions indicate that the legal responsibility of medical device business actors' legal responsibility is not limited to ensuring compliance before products are marketed but also extends to maintaining the safety, quality, and usefulness of medical devices throughout their circulation. Therefore, the effectiveness of this regulatory framework ultimately depends on consistent supervision and enforcement, particularly in ensuring that business actors fulfill their obligations and that patient safety remains the primary consideration in the distribution and use of medical devices.

3.2. Form of Legal Responsibility of Medical Device Business Actors

The legal responsibility of medical device business actors for patient safety can be categorized based on applicable legal provisions and theories of liability. Under Article 1365 of the Civil Code, every unlawful act that causes losses to another party requires the person responsible to provide compensation. In the context of medical devices, business actors may be held liable when proven to have committed negligence or intentional acts resulting in product defects and losses to patients. The elements include an unlawful act, fault, loss, and a causal relationship between the act and the resulting loss. Article 19 of the Consumer Protection Law further emphasizes that business actors must compensate consumers for damage, pollution, and/or losses arising from goods and/or services they produce or trade. Compensation may include refunds, replacement of goods or services of equivalent value, health care, and/or other compensation in accordance with applicable laws and regulations. For medical devices, health care compensation is particularly relevant because patients harmed by defective products generally require follow-up medical treatment (Risman et al., 2024).

The concept of strict liability, or absolute responsibility, is a principle of liability that does not require proof of fault by the business actor. Article 22 of the Consumer Protection Law stipulates that the burden and responsibility of proving the existence or absence of fault in criminal cases rests with the business actor, thereby shifting the burden of proof from consumers and reflecting the principle of strict liability. Its application to medical devices is particularly relevant because of the information asymmetry between business actors and consumers, especially patients (Wajdi & Susanti, 2023). As end users, patients generally lack sufficient technical knowledge to identify medical device defects. Therefore, under strict liability, patients do not need to prove the business actor's fault but must establish the existence of a product defect and a causal relationship with the losses suffered. The Health Law also requires medical device producers and distributors to fulfill safety, quality, and usefulness requirements, with violations potentially giving rise to legal responsibility under applicable provisions.

Product liability is a form of legal responsibility for losses caused by defective products. In the context of medical devices, product defects may include design defects, manufacturing defects, and defects in warnings or instructions for use. Article 8 of the Consumer Protection Law expressly prohibits business actors from producing and/or trading goods and/or services that do not meet or comply with the required standards, do not conform to the guaranteed conditions, or do not provide information about their use in Indonesian. Article 24 of the Consumer Protection Law stipulates that business actors who sell goods and/or services to other business actors are responsible for consumer compensation claims and/or lawsuits. This provision is relevant to the medical device distribution chain, which involves manufacturers, importers, distributors, and health service facilities. Each business actor in the distribution chain may be held jointly responsible or held responsible according to their respective roles and contributions to the occurrence of losses (Yannassandi & Kongres, 2023).

In addition, Government Regulation Number 28 of 2024 regulates the obligations of business actors to recall medical devices that are proven not to meet safety and quality requirements or that pose a health risk. This recall obligation constitutes a form of preventive product responsibility aimed at preventing broader losses to patients and other users of medical devices. Law Number 17 of 2023 concerning Health provides a more comprehensive legal framework concerning the responsibilities of medical device business actors compared with the previous law. The law contains provisions concerning standards and requirements for medical devices, obligations of business actors, supervision mechanisms, and sanctions for violations. Article 153 of the Health Law requires medical devices distributed in Indonesia to have a distribution permit from the Minister of Health after undergoing a conformity assessment covering aspects of safety, quality, and usefulness (Purwodono et al., 2025).

In terms of supervision, the health law mandates an integrated medical device supervision system that includes pre-market and post-market supervision. Pre-market supervision includes technical evaluation and distribution authorization, while post-market supervision includes performance monitoring, collection of incident reports, inspections, and sample testing. Articles 389 to 394 of the Health Law contain criminal provisions applicable to business actors who distribute medical devices without a distribution permit, fail to meet quality requirements, or engage in the counterfeiting of medical devices, with the possibility of imprisonment and significant fines (Badnjević et al., 2022).

Regulation of the Minister of Health Number 62 of 2017 concerning Distribution Permits for Medical Devices, In Vitro Diagnostic Medical Devices, and Household Health Supplies regulates licensing procedures in detail. This regulation requires business actors to submit comprehensive technical data, including laboratory test

results, clinical data for high-risk medical devices, evidence of conformity with national or international standards, and labeling information and instructions for use. Failure to fulfill these requirements may result in the rejection or revocation of a distribution permit (Hidayati et al., 2020).

Patient safety is a fundamental principle in health services aimed at preventing and reducing risks, errors, and harm to patients during the health service process. Article 3 of Regulation of the Minister of Health Number 11 of 2017 concerning Patient Safety states that patient safety implementation aims to improve the quality of health care facilities through risk management. In the context of medical devices, patient safety covers the entire product life cycle, from design and production to distribution, use, and destruction. Although the legal relationship between medical device business actors and patients is generally indirect because health workers use devices, patients retain the right to seek liability for losses caused by defective products, consistent with the development of modern consumer protection law (Richards et al., 2022; Macleod, 2023). ISO 14971 also supports medical device safety by requiring systematic risk management throughout the product life cycle, including hazard identification, risk evaluation, risk control, and continuous monitoring (Elahi, 2021; Kheir et al., 2022).

3.3. Obstacles to Law Enforcement and Strengthening Efforts

Although the regulatory framework for legal responsibility for medical device business actors is quite comprehensive, the implementation of law enforcement still faces several obstacles. First, weaknesses in the post-market surveillance system (post-market surveillance). The medical device incident reporting system in Indonesia has not been running optimally. Many health care facilities lack a standardized mechanism for reporting medical device incidents, so incident data is not recorded comprehensively. This condition makes it difficult to detect problematic medical devices early (Palojoki et al., 2019; Yadav et al., 2025).

The limitation of supervisory resources. The number of medical device supervisors in Indonesia is not proportional to the volume of products and business actors that must be supervised. The capacity of medical device testing laboratories is also still limited, especially for high-tech medical device testing. These limitations affect the effectiveness of supervision at both the central and regional levels (Suriyati, 2022). The medical device distribution chain is complex. Medical devices often go through several stages of distribution before reaching the end user, involving manufacturers, importers, distributors, sub-distributors, and health care facilities. This complexity complicates the process of identifying the responsible party when an incident occurs, especially in determining whether the defect occurred during production, storage, or use.

Challenges related to technological developments. The emergence of digital-based medical devices, including SaMD, internet-connected medical devices, and artificial intelligence-based medical devices, poses new challenges in determining legal liability. Existing regulations have not fully accommodated the unique characteristics of digital health tools, such as regular software updates, the use of adaptive algorithms, and cybersecurity risks. Business actors also have a lack of legal awareness. Not a few medical device business actors, especially small and medium-scale business actors, have not fully understood their legal obligations and responsibilities in ensuring product safety and quality. The lack of socialization of regulations and coaching programs also contributes to the low level of compliance (Kheir et al., 2022).

In an effort to overcome these obstacles, several strategic steps are needed. First, strengthening the pharmacovigilance system for medical devices (*materiovigilance*) through the development of a nationally integrated and electronic-based incident reporting system. The system should include mandatory reporting mechanisms for health care facilities and business actors and provide prompt feedback for corrective

action. Second, increasing the capacity of supervisory resources through increasing the number of supervisors, increasing competence through continuous training, and modernizing testing laboratory infrastructure. Third, strengthening international cooperation in the supervision of medical devices, including through the mechanism of reliance on the results of evaluations from regulatory authorities of other countries whose capacity has been recognized (recognized regulatory authority). Fourth, the development of regulations that are responsive to technological developments, including drafting specific guidelines for digital medical devices, SaMD, and artificial intelligence-based medical devices. Fifth, increasing education and socialization to business actors regarding legal obligations and regulatory compliance standards, as well as empowering consumers (patients) to be more aware of their legal rights related to the safety of medical devices (Yadav et al., 2025).

4. Conclusion

Based on the results of the research and discussion, the study finds that the legal responsibility of medical device business actors for patient safety in Indonesia is established through a combination of liability based on fault, strict liability, and product liability. The applicable legal framework, particularly the Civil Code, Consumer Protection Law, Health Law, and Government Regulation Number 28 of 2024, provides a relatively comprehensive basis for requiring business actors to ensure the safety, quality, and usefulness of medical devices. However, the effectiveness of this framework is constrained by weaknesses in post-market surveillance, limited supervisory resources, complex distribution chains, technological developments in digital medical devices, and low legal awareness among business actors. These findings imply that patient safety protection requires stronger enforcement mechanisms, integrated *materiovigilance*, improved supervisory capacity, responsive regulation for emerging technologies, and greater regulatory education for business actors and consumers.

This study is limited by its normative legal approach, which relies primarily on legislation, legal literature, and related secondary legal materials and therefore does not empirically assess the implementation of regulations by business actors, health care facilities, or supervisory authorities implement regulations. The study also does not examine specific medical device cases in depth or compare Indonesia's regulatory enforcement with other jurisdictions. Future research should therefore complement normative analysis with empirical and comparative legal research to evaluate the practical effectiveness of medical device supervision and liability mechanisms. Further studies may also focus specifically on legal responsibility for Software as a Medical Device, artificial intelligence-based medical devices, cybersecurity risks, and cross-border medical device distribution. Such research can help develop a more adaptive and comprehensive legal framework that strengthens business accountability and ensures sustainable patient safety.

References

Badnjević, A., Pokvić, L. G., Deumić, A., & Bećirović, L. S. (2022). Post-market surveillance of medical devices: A review. *Technology and Health Care*, *30*(6), 1315–1329. https://doi.org/10.3233/THC-220284.

Bruyndonckx, A., Murovec, V., & Bulckaert, M. (2020). Product liability: Compliance and safety issues. In *HealthTech* (pp. 114–142). Cheltenham: Edward Elgar Publishing. https://doi.org/10.4337/9781839104909.00015.

Elahi, B. (2021). *Safety risk management for medical devices.* London: Academic Press.

Giragn, M., Endale, S., & Belete, A. (2025). Post-market surveillance of medical devices in Ethiopia: Implementation status, regulatory challenges, and future perspectives. *Journal*

of Patient Safety and Risk Management, *30*(3), 139–148. https://doi.org/10.1177/25160435251329 62.

Government of the Republic of Indonesia. (2024). *Government Regulation Number 28 of 2024 concerning the Implementation of Law Number 17 of 2023 concerning Health.*

Habilillah, E., & Alfath, T. P. (2026). Analisis kepastian hukum bagi perusahaan distributor terhadap izin edar alat kesehatan: Legal certainty analysis for distributors regarding marketing authorisation for medical devices. *Journal of Indonesian Comparative of Syari'ah Law*, *9*(1), 1–18. https://doi.org/10.52120/z6s2fd14.

Hidayati, N., Almasdy, D., & Putra, A. S. (2020). Global trade and health: an Indonesian perspective on the ASEAN medical device directive policy. *Public Health*, *7*(4), 100-114. https://doi.org/10.22146/bkm.60819.

Hosnah, A. U. (2021). *Karakteristik ilmu hukum dan metode penelitian hukum normatif.* Depok: Rajawali Press.

Kheir, O., Jacoby, A., & Verwulgen, S. (2022). Risk identification and analysis in the development of medical devices among start-ups: Towards a broader risk management framework. *Medical Devices: Evidence and Research*, *3*(3), 349–363. https://doi.org/10.2147/MDER.S375977.

Kusumawati, L. R., Nasir, M., & Tamrin, H. (2025). Kepastian hukum dalam penetapan standar harga alat kesehatan untuk peningkatan kualitas layanan kesehatan. *Journal of Health Law*, *1*(2), 1–21.

Macleod, S. (2023). The Independent medicines and medical devices safety review: regulatory reform and remedies. *Law, Technology and Humans*, *5*(2), 5–20. https://doi.org/10.5204/lthj.3083.

Manurung, H., Sianturi, H. M., & Isnainul, O. (2024). Implikasi hukum atas penggunaan teknologi dalam pelayanan kesehatan telemedicine. *Judge: Jurnal Hukum*, *5*(3), 91–97. https://doi.org/10.54209/judge.v5i03.806.

Ministry of Health of the Republic of Indonesia. (2017). *Regulation of the Minister of Health Number 11 of 2017 concerning Patient Safety.*

Ministry of Health of the Republic of Indonesia. (2017). *Regulation of the Minister of Health Number 62 of 2017 concerning Marketing Authorization of Medical Devices, in Vitro Diagnostic Medical Devices, and Household Health Supplies.*

Ministry of Health of the Republic of Indonesia. (2018). *Regulation of the Minister of Health Number 4 of 2018 concerning Hospital Obligations and Patient Obligations.*

Muhtar, M. H., Pedrason, R., & Harryarsana, I. G. K. B. (2023). Human rights constitution on health protection of Indonesian citizens. *Russian Law Journal*, *11*(2), 149–160.

Nadapdap, C. A., Raffles, R., & Manik, H. (2022). Hak hukum terhadap konsumen penggunaan alat kesehatan pencegah Covid-19 Ilegal. *Zaaken: Journal of Civil and Business Law*, *3*(3), 353-377. https://doi.org/10.22437/zaaken.v3i3.18064.

Palojoki, S., Saranto, K., & Lehtonen, L. (2019). Reporting medical device safety incidents to regulatory authorities: An analysis and classification of technology-induced errors. *Health Informatics Journal*, *25*(3), 731–740. https://doi.org/10.1177/1460458217720400.

Pratono, A. H., & Ratih, R. V. S. (2019). International alliance strategies: A case study of the Indonesian medical device industry. In *Globalization and development: Entrepreneurship, innovation, business and policy insights from Asia and Africa* (pp. 381–400). Cham: Springer International Publishing. https://doi.org/10.1007/978-3-030-11766-5_15.

Prawira, A. W., & Qolbi, S. (2025). Strategic adaptation and sustainable growth in Indonesia's medical device industry: A PESTEL-based conceptual analysis of industry dynamics and firm-level capabilities. *Andromeda: Jurnal Manajemen dan Bisnis Syariah*, *3*(2), 297–312. https://doi.org/10.24260/cet5cr64.

Purwodono, I. J., Muaja, H. S., & Kaswenda, V. D. D. (2025). Tindak pidana memproduksi atau mengedarkan sediaan farmasi dan/atau alat kesehatan yang tidak memenuhi standar menurut Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan. *Lex Privatum*, *15*(2), 90-106.

Rayyan, R., & Siregar, A. R. M. (2025). Kepastian hukum dalam penerapan teknologi kesehatan: Perlindungan data pasien dan malpraktik. *Politika Progresif: Jurnal Hukum, Politik dan Humaniora*, *2*(1), 1–11. https://doi.org/10.62383/progres.v2i1.1230.

Rayyan, R., Zarzani, T. R., & Simarmata, M. (2025). Efforts to fulfill and ensure legal protection of patients' rights in healthcare services. In *Proceedings of International Conference on Islamic Community Studies* (pp. 4034–4045). Medan: Universitas Pembangunan Panca Budi.

Republic of Indonesia. (1945). *The 1945 Constitution of the Republic of Indonesia.*
Republic of Indonesia. (1999). *Law Number 8 of 1999 concerning Consumer Protection.*
Republic of Indonesia. (2023). *Law Number 17 of 2023 concerning Health.*
Richards, B., Jacobson, S. S., Lotz, M., & Rogers, W. (2022). The regulation of medical device representatives: A question of trust? *Law, Technology and Humans*, *4*(1), 117–131. https://doi.org/10.5204/lthj.2281.
Risman, R., Darmawan, D., Khayru, R. K., Saktiawan, P., & Mujito, M. (2024). Construction of consumer rights and business liability for losses resulting from defective or dangerous medicines and medical devices in Indonesian positive law. *Journal of Social Science Studies*, *4*(2), 333–350.
Sahidu, S., Putra, A. R., & Darmawan, D. (2023). Medical advertising regulations and patient protection as consumers of healthcare services. *Journal of Social Science Studies*, *3*(1), 331–342.
Sari, N. E., & Fikri, A. M. M. (2025). The supremacy of patient safety: Juridical and empirical analysis of emergency medical care. *Research Horizon*, *5*(6), 3117-3126. https://doi.org/10.54518/rh.5.6.2025.860.
Sun, J., Wu, K., Liu, B., & Zhang, S. (2021). IMDRF essential principles of safety and performance of medical devices and IVD medical devices: Introduction and consideration. *Chinese Journal of Medical Instrumentation*, *45*(1), 62–66. https://doi.org/10.3969/j.issn.1671-7104.2021.01.013.
Suriyati, C. (2025). Tanggung jawab pelaku usaha atas produk cacat dalam perspektif hukum perlindungan konsumen. *Jurnal Ilmu Hukum*, *1*(1), 1–7.
Wajdi, F., & Susanti, D. (2023). *Hukum perlindungan konsumen.* Jakarta: Setara Press.
World Health Organization. (2003). *Medical device regulations: Global overview and guiding principles.* Geneva: World Health Organization.
Yadav, A. R., Pawar, A. R., Shete, A. S., Jadhav, N. R., Kumbhar, A. R., Jadhav, N. M., & Gejage, S. M. (2025). Comparative analysis of medical device adverse event reporting forms for patients and industries across various countries, and the introduction of a unified generic form for harmonization. *Expert Review of Medical Devices*, *22*(1), 49–62. https://doi.org/10.1080/17434440.2025.2451409.
Yannassandi, M. N., & Kongres, E. (2023). Perlindungan hukum terhadap konsumen atas penjualan screw orthopedi tanpa melalui uji kelayakan dan izin edar. *Jurnal Hukum Magnum Opus*, *6*(1), 47-58. https://doi.org/10.30996/jhmo.v6i1.7389.

Acknowledgment
We gratefully acknowledge the contributions of individuals who supported the completion of this article.

Funding Information
This research did not receive any funding.

Conflict of Interest Statement
The authors declare that there is no conflict of interest.

Ethical Approval and Originality Statement
Ethical approval was obtained for this study. The manuscript represents original work and has not been previously published, nor is it under consideration by another journal.

Data Disclosure Statement
The data that support the findings of this study are available from the corresponding author upon reasonable request.