ENSURING TRUST IN HEALTHCARE: COMBATTING FAKE MEDICAL EQUIPMENT IN INDIA

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INTRODUCTION

The Healthcare Sector in India is the most Sensitive and Vulnerable in India. And holds the trust of about 1.25 crore people of India. But the problem of Counterfeit medical devices in India's healthcare sector is rapidly increasing. According to the World Health Organisation (WHO), in the year 2024-25, for each 10 medical devices in India, at least 1 Machine was found to be Counterfeit. This issue is not unique to India, with global estimates indicating that at least 20-25% of counterfeit cases originate from India.

The legal query concerning vendor liability for supplying counterfeit or substandard medical equipment to hospitals is primarily addressed via statutory provisions and judicial precedents related to consumer rights, criminal negligence, and regulatory compliance. The Consumer Protection Act, 2019, through its product liability provisions (Sections 2(1)(o), 85), enables affected patients or hospitals to sue manufacturers, sellers, and service providers jointly or severally for defective medical devices causing harm. Courts have recognised these claims even without proof of negligence or fraud, establishing strict liability for defective products.

There have been instances where many of these Counterfeit medical devices have gone unnoticed, maybe due to a lack of expertise or knowledge. This situation gives rise to more unlawful activities like these. When a medical device fails and causes harm, the fundamental question that arises is: who is responsible?[1] This question arises because for the medical device to cause harm, there must be its usage, and the one using the machine must be a medical professional. The answer to this question depends on the nature of the failure and the extent of

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[1] Mahip Singh, 'Medical Device Failures in India — Determining the Liability' (SCC Times, 10 February 2025) <https://www.scconline.com/blog/post/2025/02/10/medical-device-failures-in-india-determining-the-liability/> accessed 17 August 2025.

negligence. Liability may be attributed to three Key Parties: The Manufacturer, The Doctor, and the hospital.

Typically, the first party held accountable is the Manufacturer. The Consumer Protection Act, 2019, enshrines product liability of the manufacturer, meaning that manufacturers are responsible for any harm caused by defective products.[2] Section 2(1)(f) in The Consumer Protection Act, 1986,[3] defines defect as: any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or under any contract, express or implied, or as is claimed by the trader in any manner whatsoever in relation to any goods. So, these defects do not only mean the faulty Manufacture, but also any flaws in design, inadequate instructions or warnings could lead to a product default, ultimately amounting to Negligence.

The Medical Devices Rules 2017 mandate the Manufacturer to obtain approval from the Central Drugs Standard Control Organisation (CDSCO) before marketing any device. If any inconsistencies have been found in failing to comply with the provisions of the act, then the manufacturer may be held Liable. However, while the manufacturer holds the primary responsibility for faulty devices, Hospitals can also be held liable. This is particularly the case when hospitals fail to ensure the proper handling, maintenance, and monitoring of the devices they use. The Clinical Establishments Regulations Act, 2010 maintains that the Hospitals are required to practice strict safety and quality standards, including performing routine servicing and adhering to manufacturer guidelines, including performing routine servicing, and adhering to manufacturer guidelines.

Similarly, Doctors and other Healthcare Providers play an equally important role in ensuring the smooth functioning of medical devices. While they are not particularly responsible for the device's manufacturing defect, inconsistency in ensuring due diligence when selecting, operating, or monitoring the device may hold them Liable. According to The Indian Penal Code[4] Criminal negligence charges can be levied if the reckless or improper use of a device

[2] Mahip Singh, 'Medical Device Failures in India — Determining the Liability' (SCC Times, 10 February 2025) <https://www.scconline.com/blog/post/2025/02/10/medical-device-failures-in-india-determining-the-liability/> accessed 17 August 2025
[3] The Consumer Protection Act 1986, s 2(1)(f) (Indian Kanoon, 31st January 2017) <https://indiankanoon.org/doc/147181408/> accessed on 17 August 2025
[4] Indian Penal Code, s 304-A [Now Bhartiya Nyaya Sanhita 2023, s 106(1)]

results in patient harm. However, simply making an error in judgment does not constitute criminal negligence unless it amounts to gross recklessness.

Under the IPC, criminal liability arises under negligence provisions (Section 304A and Sections 336-338) if defective devices cause injury or death due to reckless or negligent acts by vendors or hospitals. Hospitals must exercise due diligence in procurement and maintenance; failure exposes them to negligence claims. The Drugs and Cosmetics Act, along with Medical Device Rules, mandates licensing, safety evaluations, and clinical data for medical devices; non-compliance attracts criminal and civil penalties.

HOW TO ACQUIRE A MEDICAL DEVICE IN INDIA?

The Central Drugs Standard Control Organisation (CDSCO) administers the Regulations of the Medical Devices in India,[5] under the Directorate General of Health Services in the Ministry of Health and Welfare. The CDSCO is the National Regulatory Authority (NRA) of India.

Medical Devices in India are classified into five categories: Class A (Non-Measuring/Sterile), Class B (Measuring/ Sterile), Class C and Class D based on risk level. The machines are classified based on intended Use, Duration of contact with the Body, and Invasiveness. The application process of these medical devices is based on the Classification. Except for the Class A (N-M/S) machine, the application requires 6 to 8 Months based on Risk Factors. Class A machines just need to be registered in the e-Portal and may be Imported Accordingly.

The process of acquiring a medical device follows-

Classification: First, the Sponsor must determine the device class (A-, low, B-low-moderate, C-moderate-high, D-high) using the CDSCO risk-matrix (e.g., Class A non-sterile, non-measuring devices are exempt from an import licence).

Local representation: A foreign manufacturer must appoint an Indian Authorised Agent (IAA) who holds a valid wholesale or manufacturing licence and will submit all documents on the SUGAM portal.

Technical dossier: The applicant must prepare a Device Master File (DMF) and Plant Master File (PMF) containing device description, risk-management, clinical-evaluation (if required),

[5] Medical Device Regulation In India (Asia Actual) <https://asiaactual.com/india/medical-device-registration/> accessed on 17 August 2025

ISO 13485 certification, Free-Sale Certificate, labelling, and a predicate table (or Form MD-26 for novel devices).

Application: For import, Form MD-14 (or MD-15 after approval) is filed with the required fees; for manufacturing, Form MD-3/MD-7 is used. The application is reviewed for completeness and then examined by the Central Licensing Authority (CLA) for Class C/D or by the State Licensing Authority (SLA) for Class A/B.

Review & timelines: CDSCO aims to grant an import licence (Form MD-15) within nine months, but queries may appear after 3-4 months and must be answered within 45 days; the query-response period is not counted in the nine-month deadline.

Post-approval: Licences are perpetual if the retention fee is paid every five years; failure to pay incurs a 2 % monthly penalty and possible cancellation. However, there also exist common loopholes, which may, in some cases, give manufacturers a free hand.

Exemptions and self-certification: Class A non-measuring/sterile devices are exempt from MD-15, allowing self-certified import without detailed scrutiny.

Delayed query handling: CDSCO may pause the timeline while seeking clarification, effectively extending the approval period beyond the statutory nine months.

Reliance on foreign approvals: Devices approved in the US/EU can be registered with limited local data, creating a "regulatory shortcut" that may bypass rigorous Indian clinical evaluation.

Lack of UDI implementation: The Unique Device Identification system remains unimplemented, limiting traceability and post-market surveillance.

Ambiguous classification: Subject-expert-committee (SEC) decisions on novel devices can be inconsistent, leading to unpredictable requirements and delays.

PREVENTIONS WHICH CAN BE EXERCISED TO MITIGATE LIABILITY

By the Manufacturer: The Manufacturer holds the primary Liability and responsibility to import up-to-date medical devices to the medical Institutions. They must conduct regular quality checks, conduct thorough testing, and implement control measures. It is necessary to comply with the Medical Devices Rules, 2017. There is a necessity to provide clearer instructions and warnings on these medical devices to ensure Trust, Smooth Functioning and

increase the success rate of patient treatment. The National Regulatory Authority (NRA) of India, CDSCO, must also conduct regular checks to eliminate any irregularities practised by the Manufacturers and ensure Trust among Medical Institutions.

By the Medical Institutions: The most well-known medical institutions in India are Hospitals. They must be well-updated with the dynamic medical field. Medical devices play a crucial role in device management and the regulation of medical devices. There must be regular Inspections, Servicing and Technical checks by the Hospital. Strict Compliance with the Legal Regulations must be ensured; any non-compliance can impose Liability on the Institution. Implementation of a standardised monitoring device for tracking device performance and addressing technical Issues promptly.

By the Doctors and Medical Professionals: The Patient's well-being must be the primary objective of the professionals. Which will start with the medium through which they are treating the patients. They must use only approved Devices, well-maintained devices and exercise caution while operating them. They should closely monitor patients for any device-related complications and promptly report adverse events to the Materiovigilance Programme of India (MvPI). Obtaining professional indemnity insurance can further safeguard them from potential legal claims. As medical devices increasingly incorporate artificial intelligence (AI) and software-driven mechanisms, medical professionals must also stay informed about potential risks associated with algorithmic errors or cybersecurity threats, particularly in robotic-assisted surgeries and digital diagnostic tools.[6]

CONCLUSION

Medical device failures raise complex legal and ethical questions, requiring a multifaceted approach to liability prevention, making it essential for all stakeholders to take proactive measures to ensure patient safety and reduce liability risks. Strict quality control, regular maintenance, comprehensive staff training, and adherence to regulatory guidelines are essential to prevent harm. As the healthcare industry evolves with technological advancements, such as AI-driven devices and cybersecurity concerns, all stakeholders must stay vigilant and adapt to

[6] Mahip Singh, 'Medical Devices Failure in India-Determining the Liability'(SCC Times, 10 February 2025) <https://www.scconline.com/blog/post/2025/02/10/medical-device-failures-in-india-determining-the-liability/> accessed on 17 August 2025

emerging challenges. By fostering a culture of accountability and compliance, the healthcare system can better protect patients and mitigate legal risks.

In areas of rapid technological change, such as 3D printing and driverless cars, the existing principles of product liability in India are still not sufficiently evolved to identify and apportion liability in cases involving human and machine error. The issue of liability is even less clear in situations where the involvement of a human element is reduced and important decisions are taken by artificial intelligence systems. However, in spite of the challenges presented by such rapid change, legislators and the judiciary are continuously attempting to keep Indian laws updated.[7]

[7] Vivek Bajaj, 'Product Liability Laws in India' (AZB & Partners, 07 July 2020) <https://www.azbpartners.com/bank/india-product-liability-2020/> accessed on 17 August 2025