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REVIEW ARTICLE

Navigating the legal and regulatory landscape for digital pathology in Malaysia

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Abstract

The transition from traditional microscopy-based diagnostic workflows to digital pathology for primary diagnosis necessitates a robust understanding of the applicable legal and regulatory frameworks. This review synthesises the multi-layered regulatory landscape governing digital pathology adoption in Malaysia. Key statutory and professional requirements are examined, including the Medical Device Act 2012 for system registration; MS ISO 15189 and STR 2.2 for laboratory accreditation and clinical validation; and the Malaysian Medical Council's 2024 Telemedicine Guideline for its implications on telepathology practice. In addition, the integration of digitised slides into formal medical records is considered under the Private Healthcare Facilities and Services Regulations 2006, alongside data privacy obligations under the Personal Data Protection Act 2010 and evidentiary admissibility requirements under the Evidence Act 1950 Malaysia. This review underscores that safe and legally compliant implementation of digital pathology requires rigorous system validation, strict data security protocols, appropriate institutional credentialing, and comprehensive audit trail maintenance.

Keywords: digital pathology, medical device act, regulatory compliance

INTRODUCTION

Digital pathology represents a technological transformation in the acquisition, presentation, and interpretation of anatomic pathological information. Although its fundamental purpose remains unchanged—the generation of visual data for diagnostic interpretation—the mode of acquisition and presentation differs from conventional microscopy. The diagnostic substrate in both settings remains the visual information; however, digital pathology replaces the conventional light microscope with image scanners and viewing software for on-screen evaluation. This shift extends the traditional microscopy-based workflow into a digitised environment, enabling remote access, image sharing, archival storage, and computational analysis, while preserving the central role of morphological assessment by the pathologist.[1] This transition also introduces regulatory complexity, reflecting a multi-layered governance structure spanning device regulation, laboratory accreditation, professional conduct, data governance, and evidentiary law.

The 2017 U.S. Food and Drug Administration (FDA) approval of Whole Slide Imaging (WSI) for clinical use marked a pivotal shift, establishing its diagnostic non-inferiority to traditional glass slide microscopy in validated settings and elevating it from a research tool to a primary diagnostic modality.[2] A parallel regulatory evolution is underway in Malaysia, and an understanding of the applicable legal framework is essential for every pathologist engaged in, or transitioning to, digital reporting.

Digital pathology in Malaysia is primarily governed by the Medical Device Act 2012 (Act 737).[3] Beyond device registration, the digital workflow intersects with several additional statutes: the Private Healthcare Facilities and Services Act 1998 (Act 586), the Personal Data Protection Act 2010 (Act 709), and the Evidence Act 1950 (Act 56).[4-6] The Pathology Laboratory Act 2007 (Act 674) and the Telemedicine Act 1997 (Act 564) address relevant aspects of the workflow but remain unenforced.[7,8] Laboratories must also conform to accreditation standards such as MS ISO 15189, and all pathologists are

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bound by the professional and ethical guidelines of the Malaysian Medical Council (MMC). This review adopts an Act-by-Act approach to these regulatory domains, outlining their respective functions and highlighting the practical implications for pathologists and laboratory directors implementing or operating digital pathology services.

Medical Device Act 2012 (Act 737)

Function: Regulates market entry and technical validity of digital pathology systems.
Under the Medical Device Act 2012 (Act 737), a "medical device" broadly includes any instrument, machine, or software intended for the diagnosis, prevention, monitoring, treatment, or alleviation of disease.[3] Digital pathology systems, comprising hardware scanners, image displays or viewers, and analysis software, fall squarely within this definition, as their primary purpose is the clinical diagnosis of disease from human specimens.

The key compliance requirements are detailed in Section 5 of Act 737:

- Section 5(1): Prohibits the import, export, or placement of any medical device on the market unless it is officially registered with the Medical Device Authority (MDA).
- Section 5(2): Specifies that contravention carries a fine of up to RM200,000, imprisonment for up to three years, or both.

Therefore, before vendors place a digital system on the market, they must apply for medical device registration. This necessitates passing a conformity assessment and a performance evaluation to verify that the device meets its intended clinical and technical specifications. Separately, the manufacturer must ensure the device is produced in accordance with Good Manufacturing Practice standards. Conversely, laboratories must verify with vendors that the entire digital pathology ecosystem—including scanner hardware, display monitors, viewing software, and AI modules—is duly registered with the MDA prior to clinical implementation. Table 1 lists key registered systems as of April 2026.

TABLE 1: Selected Medical Device Authority (MDA)-Registered Digital Pathology Systems in Malaysia

Device Name	Registration No.	Grouping	Workflow Scope	Key Components / Description
VENTANA DP 600 Slide Scanner	IVDA8144823-128151	Single	Single Instrument	High-capacity (240 slides); scan application with embedded quality-checking viewer.
VENTANA DP 200 Slide Scanner	IVD52652863918A / IVDA10713526-228874	Single	Single Instrument	Up to 6 slides; scanner unit with control PC for quality checks.
navify Digital Pathology Software	IVDA3381119-37489	Family	Software Workflow	Web-based viewer for managing and sharing slides; LIS-interfaced.
3DHISTECH Digital Slide Scanner	IVDA8524325-198985	Family	Series of Instruments	Single to 1,000-slide capacity; brightfield and fluorescence.
3DH Pannoramic DX Series	IVDA3998625-216211	Family	Series of Instruments	High-throughput scanners for demanding diagnostic environments.
KFBIO Digital Slide Scanner	IVDA7812423-143637	Family	Series of Instruments	Auto-loading brightfield and fluorescence.
Epredia E1000 Digital Pathology Solution	IVDA3564324-190746	System	Whole Workflow	Scanner, Image Management System (IMS), viewer software, and display.
Genedian Digital Pathology Slide Scanner	IVDA9455723-128688	Family of System	Whole Workflow	Scanner models DS120/DS600/ DS12, slide holders, full computer workstation.
Aperio GT 450 DX Slide Scanner	IVDA2527122-109410	System	Whole Workflow	450-slide scanner paired with Aperio WebViewer DX software.
Barco NV	IVDA2817525-217879	Family	Single Instrument	MDPC-8127- Ultra-high-definition medical grade display for digital pathology

Note: Registered digital pathology systems were sourced from the Malaysia Medical Device Register (MMDR) via its public search portal (https://mdar.mda.gov.my/). Results are based on keywords "slide scanner" and "display" as of April 2026.

Pathology Laboratory Act 2007 (Act 674) and MS ISO 15189

Function: Governs laboratory quality, validation, and operational competence.

Compliance with Medical Device Act 2012 establishes the technical validity of the system but does not in itself permit clinical deployment. The Pathology Laboratory Act 2007 (Act 674) provides a legislative framework for the governance of private pathology laboratories, with Part IX addressing quality requirements.[7,9] As Act 674 has not been operationalised through subsidiary regulations, accredited laboratories in both the public and private sectors under the national unified laboratory accreditation scheme, known as Skim Akreditasi Makmal Malaysia (SAMM), rely on accreditation standard MS ISO 15189:2022 Medical Laboratories - Requirements for Quality and Competence as the de facto benchmark for quality and competence, as administered by the Department of Standards Malaysia.[10]

The introduction of digital pathology is treated as the adoption of a new examination method within the existing scope of laboratory accreditation. The Department of Standards Malaysia provides supplementary guidance through the STR 2.2: Specific Technical Requirements for Accreditation of Anatomical Pathology.[11] This guidance explicitly mandates that laboratories using digital microscopy for diagnostic purposes maintain:

- Standard Operating Procedures (SOPs): Covering the entire digital chain from slide selection and scanning to final reporting.
- Supporting Documentation: Technical logs and quality control records specific to digital imaging and monitor calibration.
- Formal Training Records: Documented evidence of staff and pathologist competency in digital interpretation and system troubleshooting.
- Validation Study: A formal study demonstrating non-inferiority of digital diagnoses compared to traditional glass-slide microscopy.

Validation Framework

For clinical validation in particular, the College of American Pathologists (CAP) guideline

Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology — developed with the American Society for Clinical Pathology and Association for Pathology Informatics — is widely regarded as the international gold standard.[12] Recommendations from the Royal College of Pathologists of the United Kingdom (RCPath, UK) and the Royal College of Pathologists of Australasia (RCPA) also provide useful benchmarks and are referenced in STR 2.2.[11,13,14] A critical principle is that validation must be specific to the intended use:

- Primary Diagnosis: Where the digital slide entirely replaces the glass slide for the primary diagnostic report. This requires the most stringent validation — typically a minimum of 60 cases per diagnostic application and a documented washout period to prevent recall bias.[12]
- Secondary Use: Uses such as remote second opinions, frozen section review, or immunohistochemistry (IHC) quantification must each be validated separately. A system validated for primary diagnosis is not automatically fit for other purposes.[13]

Telepathology and the Telemedicine Act 1997 (Act 564)

Function: Defines professional responsibility and standard of care in remote practice.

While MS ISO 15189 and validation standards define laboratory competence for digital pathology, telepathology as an extension of digital pathology introduces additional regulatory and professional considerations. The Telemedicine Act 1997 (Act 564) was enacted to regulate medical practice via audio, visual, and data communications.[8] As this Act remains unenforced, registered medical practitioners are instead governed by the MMC Guideline on Telemedicine 2024, which replaces the pandemic-era Advisory on Virtual Consultations.[15] The 2024 guideline defines telemedicine as the delivery of medical services via information and communication technology (ICT) in accordance with the Code of Professional Conduct 2019.[16] While the 2024 guideline is framed around the practitioner–patient dyad, its foundational ethical and professional principles are modality-agnostic. In telepathology, the "patient encounter" is mediated through digitised slides, but the duty of care, standard of practice, and accountability remain unchanged. Accordingly, the Principle of Equivalency remains applicable and must be interpreted within the context of digital diagnostic workflows.

Remote Primary Diagnosis — The Principle of Equivalency

When digital pathology is used for remote primary diagnosis, the quality and standard of care delivered via ICT must be identical to that of traditional microscopic diagnosis. Pathologists must therefore observe three key pillars:

- Validation and Technical Integrity: Remote reporting in telepathology requires proof of technical consistency equivalent to on-site systems. Network stability and remote display performance must be validated. Medical devices at remote sites, including monitors used for primary diagnosis, are not exempt from compliance with Act 737 requirements.
- Credentialing and Privileging: The pathologist must be formally credentialed and granted specific reporting privileges by the source institution — the facility where the specimen originated — ensuring the practitioner operates within that institution's quality assurance and administrative framework.
- Liability and Indemnity: The pathologist retains full legal responsibility for the rendered diagnosis. Professional indemnity insurance must explicitly cover "telemedicine" or "remote reporting" from specified off-site locations, including a private residence or home office.

Remote Secondary Opinions and Consultations

Digital pathology is also widely used for remote second opinions and expert consultations rather than primary diagnosis. The RCPath guideline provides an important framework here: when an expert opinion is sought, the ultimate responsibility for evaluating that advice — and deciding whether to incorporate it into the final diagnostic report — rests solely with the primary reporting pathologist.[13]

Private Healthcare Facilities and Services (PHFS) Regulations 2006 (subsidiary legislation under Act 586)

Function: Establishes ownership, custody, and retention of medical records.

Once digital pathology is adopted for clinical use, an additional component of the medical record is generated in the form of digitised whole slide images and their associated digital diagnostic outputs. These digitised images are not merely files but formal components of a patient's medical record, governed by the Private Healthcare Facilities and Services (PHFS) Regulations 2006 (subsidiary legislation under Act 586) and the MMC Guideline on Medical Records and Medical Reports 002/2006.[17,18] Under Section 1.2 of MMC Guideline 002/2006, a medical record comprises both intellectual and physical items. In digital pathology, this includes the WSI (classified as an imaging record) and the histopathological report derived from it. Under the Sixth Schedule of the PHFS Regulations 2006, these digital items constitute the results of relevant diagnostic tests and must be integrated into the patient's formal medical record.

The key operational obligations are:

- Server Custody: Medical records remain the property of the facility.[17] As such, all WSIs must remain under the custodial control of the facility, whether on-premises or through compliant managed infrastructure.
- No Removal of Original Data: Original records shall not be removed from the facility.[17] In a digital workflow, the primary image data on the host server must remain under institutional control.
- Retention Periods: The Malaysian College of Pathologists recommends a minimum seven-year retention period for digital scanned slides.[19] This recommendation aligns with the six-year limitation period for medical negligence actions under Section 6(1) of the Limitation Act 1953 (Act 254).[20]
- Paediatric Patients: Under the Age of Majority Act 1971, the age of majority is defined as 18 years.[21] Accordingly, medical records for minors should be retained for an additional seven years after reaching majority, i.e., until 25 years of age.[19]
- Patients Without Legal Capacity: For individuals lacking legal capacity, indefinite retention of patient data and reports is strongly advisable.[19]

Personal Data Protection Act 2010 (Act 709)

Function: Regulates data privacy, consent, and security obligations.

In addition to medical record ownership and retention requirements, digital pathology introduces distinct legal obligations concerning data privacy, consent, and security under the Personal Data Protection Act 2010 (Act 709). Under Section 4, information relating

to an individual's physical or mental health is classified as Sensitive Personal Data.[5] WSIs linked to identifiable patient information, together with accompanying clinical histories and histopathology reports, fall within this category, thereby triggering enhanced processing conditions and security safeguards.

Consent and the Clinical-Purpose Exemption

Processing sensitive personal data generally requires explicit consent. However, Section 40(1)(b) of Act 709 permits processing without explicit consent where it is necessary for medical diagnosis, provision of care, or management of healthcare services, and is carried out by a registered healthcare professional or a person under an equivalent duty of confidentiality. This exemption enables routine diagnostic telepathology, including remote reporting and consultation, without requiring repeated patient consent, provided the purpose remains strictly within clinical care.

Security Obligations

Reliance on the Section 40 exemption does not waive the Security Principle under Section 9 of Act 709. Data users must safeguard sensitive data against loss, misuse, modification, and unauthorised access. In a telepathology context this requires:

- Technical Safeguards: Encryption of data in transit and at rest, controlled access mechanisms, and secure network infrastructure.
- Operational Controls: Secure reporting environments, restricted physical and digital access, and prevention of inadvertent exposure of patient data during remote review.

Under Section 40(3), failure to comply with the conditions governing sensitive personal data processing is an offence. Misuse of diagnostic data beyond permitted medical purposes may attract fines of up to RM200,000, imprisonment for up to two years, or both.

Evidence Act 1950 (Act 56)

Function: Determines legal admissibility and evidentiary weight of digital slides.

Beyond data governance and security obligations, digital pathology also carries implications for medico-legal proceedings, particularly with respect to the admissibility and evidentiary value of digital records under the Evidence Act 1950 (Act 56). Under the Act 56, WSIs and digital records are classified as "documents produced by a computer," a definition encompassing any data recorded, stored, or processed within a digital framework.[6] Their legal standing rests on two distinct statutory requirements: admissibility (the right to be presented) and probative weight (the credibility of the content).

1. Statutory Admissibility

Under Section 90A of the Act, a digital record is admissible if it is produced during the system's "ordinary use." Demonstrating this requires formal certification by an individual responsible for the management of the imaging infrastructure. This certification invokes a rebuttable presumption that the entire digital ecosystem—including scanners, servers, and diagnostic workstations—was functioning correctly during the period in question. From a laboratory management perspective, this reinforces the necessity of rigorous validation protocols and standardised operating procedures to ensure that digital outputs are recognised as reliable records.

2. Probative Weight

While admissibility allows for the presentation of digital data, Section 90B governs the subsequent evaluation of its probative weight—the degree of credibility assigned to the evidence. The reliability of a WSI is evaluated based on the circumstances of its creation, the accuracy of the data entry, and the temporal proximity of the recording to the actual diagnostic event. Furthermore, the integrity of the data is scrutinised for any potential for misrepresentation. In practice, maintaining high probative value requires a verifiable chain of custody, immutable system audit logs, and technical safeguards that ensure data remains resilient against alteration.

Consequently, WSIs are not regarded merely as digital substitutes for traditional glass slides. Their effectiveness within a professional framework depends on the intersection of statutory certification under Section 90A and the demonstrated system integrity under Section 90B, achieved through comprehensive validation and audit protocols.

Regulatory Framework for Digital Pathology in Malaysia

As illustrated in FIGURE 1, the regulatory landscape for digital pathology in Malaysia is

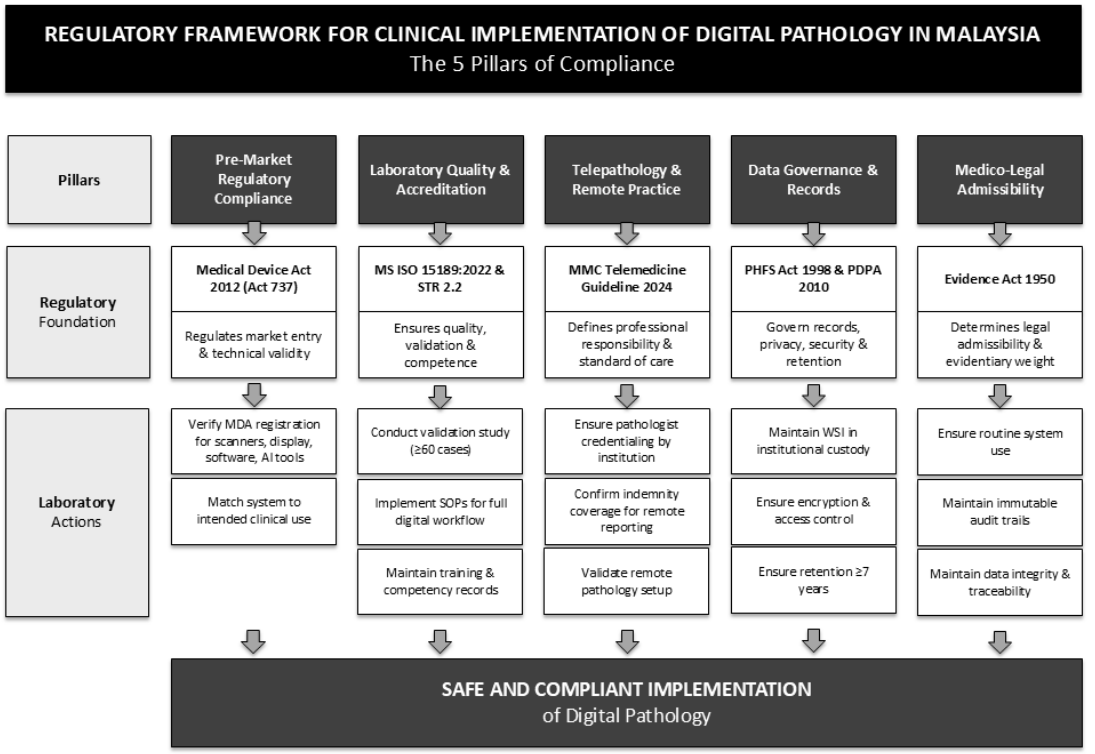

FIGURE 1. Regulatory Framework for Clinical Implementation of Digital Pathology in Malaysia. This flowchart delineates the five core pillars of compliance—Pre-Market Regulatory Compliance, Laboratory Quality & Accreditation, Telepathology & Remote Practice, Data Governance & Records, and Medico-Legal Admissibility—required under Malaysian regulations to ensure a safe and legally sound digital diagnostic workflow. WSI= Whole Slide Imaging, SOP= Standard Operating Procedures, MDA= Medical Device Authority.

multifaceted, comprising statutes from multiple government agencies. This framework is built upon five core pillars of compliance: Pre-Market Compliance, Laboratory Accreditation, Telepathology Practice, Data Governance, and Evidentiary Admissibility. Stakeholders must recognise that the implementation of digital pathology is not confined to the laboratory setting but encompasses the broader healthcare ecosystem. Consequently, due diligence is required regarding infrastructure and resource management to safeguard data confidentiality and maintain evidentiary integrity. Furthermore, digitised slides must be managed within a system that ensures long-term accessibility in strict accordance with statutory retention requirements.

Nevertheless, several unresolved grey zones persist where technological adoption outpaces statutory clarity in the current regulatory framework. Key ambiguities include whether digitised whole-slide images or physical glass slides constitute the legal "original" medical record, complicating digital-first archival policies. Liability also remains undefined when laboratories integrate mismatched, multi-vendor systems outside the closed-loop configurations validated under the Medical Device Act 2012. Additional uncertainties surround the absence of mandated technical standards for remote reporting environments. Collectively, these gaps underscore the need for targeted regulatory updates to safeguard professional accountability and evidentiary integrity.

CONCLUSION

The regulatory framework governing digital pathology in Malaysia is multi-layered, spanning device registration, laboratory accreditation, professional conduct, data protection, and evidence law. Taken together, these obligations serve a single purpose: ensuring that digital pathology delivers diagnostic care of the same quality, safety, and accountability as traditional microscopy. For successful implementation,

stakeholders must prioritise rigorous validation, strict data security, appropriate institutional credentialing, and comprehensive audit trails to maintain the legal and clinical integrity of the digitized diagnostic workflow.

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