Guideline on the Regulation of Artificial Intelligence and Medical Robotics in Healthcare, Bangladesh

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Directorate General of Drug Administration
Ministry of Health and Family Welfare
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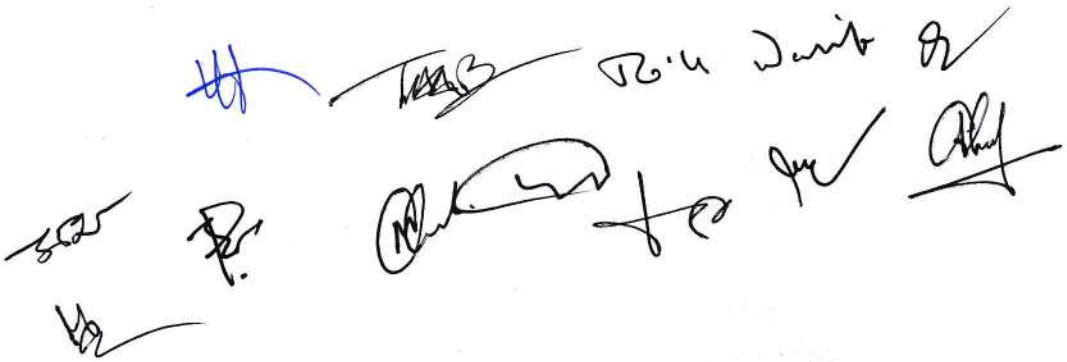


Preface:

Across the global healthcare ecosystem, including Bangladesh, Artificial Intelligence (AI) and Robotics are increasingly being applied throughout the healthcare continuum—encompassing education and training, biomedical and clinical research, healthcare administration, diagnostics, clinical decision support, therapeutic interventions, and direct patient care. These technologies have demonstrated significant potential to enhance system efficiency, support evidence-based decision-making, optimize resource utilization, and improve patient safety, quality of care, and clinical outcomes.

Nevertheless, these benefits, the deployment of AI- and robotics-enabled healthcare technologies may give rise to patient safety risks, ethical concerns, data governance challenges, algorithmic bias, and accountability issues, particularly if such systems are not appropriately designed, validated, implemented, monitored, and governed within a robust regulatory framework.

To promote safe, ethical, and effective adoption of AI and Robotics in healthcare, improve stakeholder understanding, and codify nationally relevant good practices, the Directorate General of Drug Administration (DGDA), Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh, has developed this guideline on Artificial Intelligence and Robotics in Healthcare. This guideline is intended to support developers, manufacturers, importers, distributors, healthcare institutions, researchers, and implementers involved in the lifecycle of AI- and robotics-enabled medical technologies.

This guideline complements and does not replace the existing regulatory requirements of DGDA applicable to medical devices, *in vitro* diagnostics, such as medical device import license in 2015 and Drug and Cosmetics Act, 2023 as well as other relevant national laws, rules, and standards in force in Bangladesh. They provide practical guidance on good practices related to governance, risk management, clinical evaluation, data quality, transparency, human oversight, post-market monitoring, and continuous performance management of AI and robotic systems used in healthcare.

This guideline will be reviewed and updated periodically by DGDA, as necessary, to reflect technological advancements, emerging risks, international best practices, and national

healthcare priorities. It is expected that this guideline will assist stakeholders in responsibly navigating their AI and robotics journey, while ensuring that patient safety, ethical integrity, and regulatory compliance remain paramount.

1. Executive Summary

Bangladesh is experiencing a rapid increase in the adoption of Artificial Intelligence (AI) and Robotics across multiple healthcare sectors, including diagnostics, imaging, surgery, rehabilitation, hospital automation, and public health systems. While these technologies promise improved efficiency, accuracy, and access to care, they also introduce new regulatory challenges related to safety, accountability, ethics, data governance, and cybersecurity. Existing regulatory frameworks are not fully equipped to address adaptive algorithms, autonomous systems, and software-driven medical decisions. This paper proposes a comprehensive regulatory guideline to support safe, effective, and ethical deployment of AI and Robotics in healthcare under the oversight of the Directorate General of Drug Administration (DGDA), Bangladesh.

2. Background and Context

AI- and robotics-enabled medical technologies are increasingly being deployed in both public and private healthcare facilities in Bangladesh. These include AI-assisted diagnostic tools, clinical decision support systems, surgical robots, rehabilitation robots, and hospital service robots. However, ambiguity remains regarding product classification, approval pathways, clinical validation requirements, post-market surveillance, and accountability mechanisms. A dedicated regulatory guideline is therefore essential to ensure patient safety while fostering innovation.

3. Objectives of the Guideline

The primary objectives of the proposed guideline are:

- To establish a clear regulatory framework for AI and Robotics in healthcare
- To ensure patient safety, quality, and clinical effectiveness
- To promote responsible innovation and local manufacturing
- To align Bangladesh's regulatory approach with international best practices
- To clarify the roles and responsibilities of manufacturers, healthcare providers, and regulators

4. Scope of the Guideline

This guideline establishes a regulatory, ethical, and operational framework for the safe development, approval, deployment, and post-market governance of AI- and Robotics-enabled healthcare systems, including:

- AI Medical Devices (AI-MD) / Software as a Medical Device (SaMD)/ Software in a medical device (SiMD)
- AI-driven diagnostic, monitoring, and therapeutic platforms
- Surgical, rehabilitation, and assistive robots
- Teleoperated and semi-autonomous robotic systems
- Hospital service and disinfection robots

Software as a Medical Device (SaMD) includes standalone software, standalone mobile applications, and web-based software. The framework applies to developers, manufacturers, healthcare institutions, clinicians, and regulators involved in healthcare AI and robotics.

5. Regulatory Principles

The guideline will be based on the following principles:

- Risk-based regulation based on intended use and level of autonomy
- Mandatory human oversight for moderate- and high-risk applications
- Proportional clinical validation and performance evaluation
- Transparency and explainability of AI outputs where clinically relevant
- Robust data governance, privacy, and cybersecurity measures
- Lifecycle-based regulation, including post-market surveillance
- Clear accountability and liability assignment

6. Classification Framework

AI and robotic systems will be classified into low (Class A) to High (Class D) categories based on clinical impact, autonomy, and potential harm. The classification will be based

on the existing regulatory guideline of DGDA [1]. Regulatory requirements will be proportional to risk level.

7. Lifecycle-Based Regulatory Framework

7.1 Design and Development

7.1.1 Any Artificial Intelligence–enabled or robotics-enabled healthcare product intended for medical use in Bangladesh shall be designed and developed on the basis of a clearly articulated clinical or healthcare purpose. Such purpose shall specify the intended medical indication, target patient population, clinical workflow, operating environment, and the manner in which the system is expected to support, inform, or perform healthcare functions.

7.1.2 The intended use, intended users, level of automation, degree of system autonomy, and the nature of human involvement or oversight shall be defined, justified, and documented at the design stage. These elements shall form the basis for risk classification, performance expectations, validation strategy, and regulatory evaluation.

7.1.3 Datasets used for algorithm development, including those employed for training, testing, and validation, shall be relevant to the intended use and representative of the population and clinical conditions in which the product is expected to operate. The developer or manufacturer shall take reasonable measures to ensure thavt dataset selection does not introduce unacceptable bias or limitations that could adversely affect safety or performance.

7.1.4 Where the AI model has not been trained using data representative of the Bangladeshi population, the developer or manufacturer shall be required to conduct additional validation using locally collected datasets prior to market authorization.

7.1.5 The developer or manufacturer shall establish and maintain comprehensive documentation relating to data governance, including the origin and lawful access to data, data provenance and traceability, version control mechanisms, data preprocessing and annotation methods, and identified data limitations. Where risks arising from data quality

or bias are identified, appropriate mitigation measures shall be implemented and documented.

7.1.6 AI and robotics systems shall be designed with cybersecurity considerations embedded throughout the design and development process. Such measures shall be proportionate to the system's risk classification, connectivity, and deployment context, and shall address protection against unauthorized access, data breaches, model manipulation, and system malfunction that may compromise patient safety or data integrity.

7.1.7 Where system outputs are intended to support or influence clinical decision-making, the design shall incorporate appropriate mechanisms to support transparency and interpretability. Such mechanisms shall enable users to understand the nature, limitations, and confidence of system outputs to a degree sufficient to support informed professional judgment and safe use.

7.1.7 Design and development controls shall ensure traceability between clinical requirements, identified risks, risk control measures, algorithmic design choices, and system outputs, such that the rationale for key design decisions can be reviewed and assessed by the DGDA.

7.2 Verification, Validation, and Clinical Evaluation

7.2.1 The developer or manufacturer shall generate objective evidence demonstrating that the AI-enabled or robotics-enabled healthcare product conforms to its specified requirements and performs as intended under the expected conditions of use.

7.2.2 Verification and validation activities shall be planned, executed, and documented in a systematic manner consistent with the product's intended use, technological characteristics, and risk classification, and shall form an integral part of the overall lifecycle management of the product.

7.2.3 Analytical validation shall be conducted to demonstrate the technical and functional performance of the system. Such validation shall assess performance characteristics,

including, as applicable, accuracy, precision, robustness to input variability, repeatability, reproducibility, and performance across defined operational limits.

7.2.4 Where the product performs a medical function or supports clinical decision-making, clinical validation shall be conducted to establish clinical relevance and performance in the intended use setting. Clinical evaluation methods shall be scientifically justified and appropriate to the nature of the medical claims made.

7.2.5 Clinical performance shall be assessed using metrics that are appropriate to the intended medical purpose. These may include sensitivity, specificity, positive predictive value, negative predictive value, or other clinically meaningful indicators, as justified by the clinical context.

7.2.6 The type, amount, and rigor of verification and validation evidence required shall be proportionate to the risk posed by the product, considering the degree of automation, the extent to which outputs influence or determine clinical decisions, and the potential consequences of erroneous or misleading outputs on patient safety and public health.

7.2.7 Identified limitations, uncertainty conditions, performance boundaries, and known failure modes shall be documented and, where relevant to safe use, communicated to users through labeling, instructions for use, or other appropriate means.

7.2.8 For AI-MD products developed or trained primarily on non-Bangladeshi populations, the applicant shall conduct analytical and/or clinical validation using datasets collected within Bangladesh, appropriate to the intended use and risk classification of the product.

7.2.9 Any clinical validation, as needed, shall be conducted at the expense of the applicant. The clinical research must be conducted by an independent clinical research organization (CRO) or the department of Biomedical Engineering of a public University. In either case (i) AI-MD/robotics expertise, (ii) experience in clinical research in relevant field and (iii) ethical approval body are must.

7.3 Quality Management System (QMS)

7.3.1 Developers and manufacturers of AI-enabled or robotics-enabled healthcare products shall establish, implement, and maintain a documented Quality Management System covering the entire product lifecycle, from design and development through deployment, maintenance, and post-market activities [2,3].

7.3.2 The Quality Management System shall demonstrate conformity, as applicable, with internationally recognized standards, including ISO 13485 for quality management systems [4], ISO 14971 for risk management [5], and IEC 62304 for medical device software lifecycle processes [6]. Along with these, for medical robots, IEC 80601-2-77:2019: Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment [7] and IEC 80601-2-78:2019: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation [8].

7.3.3 The Quality Management System shall include documented procedures for—

(a) design and development control;

(b) risk management and risk control verification;

(c) software and algorithm change management, including retraining or updating of models;

(d) supplier and third-party software control; and

(e) corrective and preventive actions.

7.3.4 Where AI models are modified, retrained, or updated after deployment, the Quality Management System shall ensure that such changes are systematically evaluated, documented, and controlled to confirm continued safety, performance, and regulatory compliance.

7.3.5 Records demonstrating conformity with the requirements of this section shall be retained in accordance with applicable laws and shall be made available to the DGDA upon request for the purpose of review, inspection, or regulatory assessment.

8. Pre-Market Regulatory Requirements

8.1 Product Classification and Intended Use

8.1.1 Any Artificial Intelligence–enabled or robotics-enabled healthcare product intended to be placed on the market in Bangladesh shall be subject to regulatory classification in accordance with the applicable medical device classification rules issued by the DGDA.

8.1.2 The applicant shall submit a clear and unambiguous declaration of intended use, including the medical purpose, target patient population, intended users, clinical setting, degree of automation, and the manner in which the system supports, informs, or performs healthcare functions.

8.1.3 The declared intended use shall form the basis for regulatory classification, conformity assessment pathway, evidence requirements, and post-market obligations.

8.2 Technical Documentation and System Description

8.2.1 The applicant shall submit comprehensive technical documentation sufficient to enable regulatory assessment of the safety, performance, and intended function of the product.

8.2.2 Such documentation shall include a system-level description, covering software architecture, hardware components where applicable, data flow, algorithmic components, interfaces, dependencies, and deployment environment.

8.2.3 Where the product incorporates machine learning or adaptive algorithms, the documentation shall describe the model type, training approach, update mechanisms, and any constraints placed on post-deployment modifications.

8.3 Training, Testing, and Validation Data

8.3.1 The applicant shall provide a description of datasets used for training, testing, and validation of the AI system, including data sources, size, characteristics, and relevance to the intended use.

8.3.2 The submission shall describe measures taken to ensure data quality, representativeness, and integrity, as well as known limitations of the datasets and their potential impact on system performance.

8.3.3 Where applicable, the applicant shall describe steps taken to identify and mitigate risks related to bias, data imbalance, or inappropriate generalization.

8.3.4 The regulatory submission shall clearly indicate whether the training data used are representative of the Bangladeshi population demographics. Where this is not the case, evidence of local validation conducted in accordance with Section 7.2.8 shall be provided.

8.4 Clinical Performance and Safety Evidence

8.4.1 The applicant shall submit evidence demonstrating clinical performance and safety, commensurate with the product's risk classification and intended medical purpose.

8.4.2 Such evidence shall be derived from appropriate analytical and clinical validation activities and shall demonstrate that the product achieves its intended performance without introducing unacceptable risks to patients or users.

8.4.3 The clinical evidence shall be sufficient to support the medical claims made and shall reflect the intended clinical setting and population.

8.5 Cybersecurity and Data Protection

8.5.1 The applicant shall submit a cybersecurity assessment addressing risks related to unauthorized access, data breaches, system manipulation, and service disruption.

8.5.2 Measures implemented to protect personal data, patient confidentiality, and system integrity shall be described, considering the product's connectivity, data flows, and operational environment.

8.5.3 Cybersecurity controls shall be proportionate to the potential impact of system compromise on patient safety and public health.

8.5.4 AI Medical Devices (AI-MD), including Software as a Medical Device (SaMD), that store, process, or transmit identifiable patient data shall ensure that the primary servers and

databases containing such data are physically located and maintained within the territory of Bangladesh. Transfer or storage of identifiable patient data outside Bangladesh shall not be permitted unless explicitly authorized by the DGDA.

8.5.5 AI-enabled or software-based medical systems that support remote reporting (e.g., tele-medicine, tele-radiology, tele-consultation, or remote clinical decision-making) shall implement robust mechanisms to authenticate the identity of healthcare professionals accessing or generating clinical outputs. Acceptable authentication mechanisms may include, but are not limited to, multi-factor authentication, one-time passwords (OTP), biometric or facial recognition, or equivalent secure methods appropriate to the risk and context of use.

8.6 Quality Management System Compliance

8.6.1 The applicant shall demonstrate that the product is developed and maintained under a documented Quality Management System appropriate to its nature and risk classification.

8.6.2 Evidence of conformity with applicable standards, including ISO 13485, ISO 14971, and IEC 62304, shall be submitted or made available upon request by the DGDA.

8.6.3 The Quality Management System shall support ongoing compliance, including change management, corrective and preventive actions, and post-market obligations.

For surgical robotics related products, such pre market regulatory requirement will be required for all the new facility/entity.

9. Post-market Surveillance

9.1 Real-World Performance Monitoring

9.1.1 Developers, manufacturers, and other responsible entities shall establish and maintain a post-market surveillance system to continuously monitor the real-world performance,

safety, and effectiveness of Artificial Intelligence–enabled and robotics-enabled healthcare products after they have been placed on the market.

9.1.2 Post-market surveillance activities shall be proportionate to the product's risk classification, degree of automation, and clinical impact, and shall consider real-world use conditions, user behavior, and operational environments.

9.1.3 Where feasible, performance monitoring shall include the collection and analysis of real-world data to detect performance degradation, emerging risks, unintended behavior, or deviations from expected performance.

9.1.4 For surgical robotics related products, such post market surveillance will be required for all the new facility/entity.

9.2 Adverse Event and Incident Reporting

9.2.1 Any adverse event, serious incident, or system malfunction that has resulted in, or may result in, patient harm, user harm, or unacceptable risk to public health shall be reported to the DGDA without undue delay, in accordance with applicable vigilance requirements.

9.2.2 Reportable events shall include, but shall not be limited to, incorrect or misleading outputs, system failures, cybersecurity incidents, or loss of system availability where such events may affect patient safety or clinical decision-making.

9.2.3 The responsible entity shall maintain records of all reported and non-reported incidents, investigations conducted, root cause analyses, and corrective and preventive actions taken.

9.3 Software Updates and Algorithm Change Management

9.3.1 Software updates, model retraining, algorithm modifications, and system configuration changes implemented after-market placement shall be managed under a documented change management process within the Quality Management System.

9.3.2 The responsible entity shall assess the potential impact of such changes on safety, performance, and intended use, and shall determine whether regulatory notification, approval, or re-submission is required prior to implementation.

9.3.3 Changes that may significantly affect clinical performance, risk profile, or decision-making behavior of the system shall not be deployed without appropriate validation and, where applicable, prior authorization from the DGDA.

9.4 Periodic Review of Adaptive and Learning Systems

9.4.1 For AI systems that incorporate adaptive, learning, or continuously updating functionalities, the responsible entity shall establish defined boundaries and controls governing system behavior after deployment.

9.4.2 Such systems shall be subject to periodic regulatory review, at intervals determined by the DGDA or as justified by the product's risk profile, to confirm continued conformity with approved specifications and performance expectations.

9.4.3 Documentation relating to real-world performance, algorithm updates, and risk management measures shall be made available to the DGDA upon request for the purpose of oversight and regulatory evaluation.

10. Human Resource Training and Certification

10.1 Pre-Market Training and Authorization

10.1.1 As part of the pre-market regulatory submission, the applicant shall define the intended user categories and the level of training and competency required for the safe and effective use of the AI–enabled or robotics-enabled healthcare product.

10.1.2 Where the safe use of the product depends on specialized technical, clinical, or operational expertise, the applicant shall establish a structured training and certification programme prior to market authorization.

10.1.3 The pre-market submission shall include documentation describing the training programme, including the scope of training, learning objectives, curriculum content, mode of delivery, competency assessment methods, certification criteria, and identification of designated personnel authorized to operate, supervise, or maintain the system.

10.1.4 For products determined by the DGDA to pose moderate to high risk, evidence of successful completion of required training by designated personnel may be required as a condition for market authorization or initial deployment.

10.1.5 For surgical robotics related products, such premarket notification and training will be required for all the new facility/entity.

10.2 Designation of Authorized Personnel

10.2.1 The applicant or responsible entity shall designate categories of personnel authorized to use, supervise, configure, or intervene in the operation of the AI-enabled or robotics-enabled healthcare product.

10.2.2 The scope of authorization for each category of personnel shall be commensurate with the system's level of autonomy, clinical impact, and associated risks, and shall be reflected in system access controls and operational procedures.

10.2.3 Systems enabling AI or software-based remote clinical services shall restrict access to authorized and authenticated personnel only, and shall maintain audit logs linking clinical actions and reports to verified individual users.

10.3 Post-Market Competency Maintenance and Refresher Training

10.3.1 Following market placement, the responsible entity shall ensure the continued competency of all authorized personnel throughout the operational life of the product.

10.3.2 In the case of robotics-related medical devices, particularly surgical robotic systems, suppliers/manufacturers shall establish and maintain a local office with adequate qualified personnel, including trained Biomedical Engineers. A trained Biomedical Engineer from

the supplier/manufacturer must be present during all surgical procedures utilizing the robotic system. The licensed hospital or clinic shall ensure and document compliance with this requirement.

10.3.3 Refresher training or re-certification shall be conducted at appropriate intervals and shall be mandatory where—

(a) software updates, algorithm changes, or system modifications are introduced;

(b) clinical workflows or intended use conditions are altered; or

(c) post-market surveillance identifies safety concerns, performance degradation, or use-related errors.

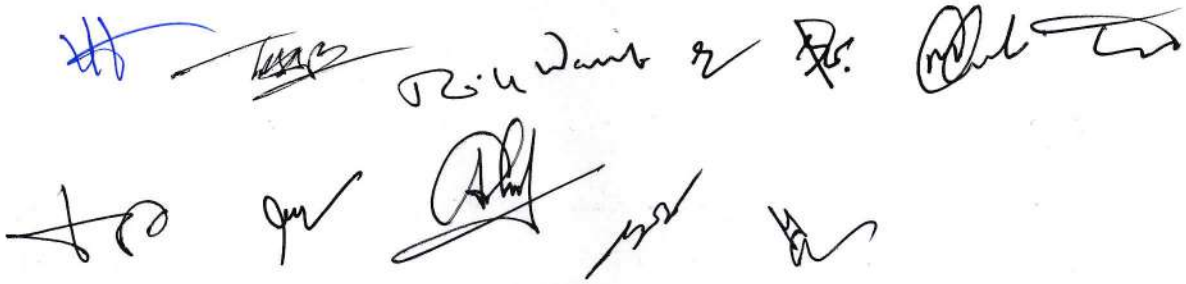
10.3.4 Training programmes shall be updated, as necessary, to reflect system changes, real-world performance data, and emerging risks identified through post-market monitoring.

10.4 Documentation and Regulatory Oversight

10.4.1 The responsible entity shall maintain complete and traceable records of training, certification, authorization, and competency assessments for all personnel involved in the use and oversight of the product.

10.4.2 Such records shall be retained in accordance with applicable laws and shall be made available to the DGDA upon request for inspection, audit, or regulatory review.

10.4.3 Failure to comply with the requirements of this section may constitute non-compliance and may result in regulatory action, including suspension of deployment, additional risk mitigation requirements, or other measures as deemed necessary in the interest of patient safety and public health.



11. Ethics, Transparency, and Patient Rights

11.1 Transparency and Disclosure

11.1.1 Healthcare providers and responsible entities shall ensure transparency regarding the use of Artificial Intelligence–enabled or robotics-enabled systems in the delivery of healthcare services.

11.1.2 Where AI or robotic systems are used to support, influence, or perform diagnostic, therapeutic, or clinical decision-making functions, patients shall be informed of the involvement of such systems in a clear and understandable manner, appropriate to the clinical context.

11.1.3 Disclosure shall include, where relevant, the role of the system in the care process, the nature of human oversight, and any material limitations of the system that may affect clinical decision-making.

11.2 Informed Consent

11.2.1 Informed consent shall be obtained from patients where AI- or robotics-assisted systems are used in clinical decision-making or interventions, in accordance with applicable laws, ethical standards, and clinical practice requirements.

11.2.2 The consent process shall provide patients with information sufficient to understand the role of the AI or robotic system in their care, the expected benefits, foreseeable risks, and available alternatives, including the option of human-only decision-making where clinically appropriate.

11.2.3 In the case of AI-only systems/software used for clinical decision support, informed consent may not be required if the clinician assumes full responsibility for the final decision and the AI tools are used only to assist.

11.3 Fairness, Bias Mitigation, and Ethical Use

11.3.1 Developers, manufacturers, and healthcare providers shall take reasonable measures to identify, assess, and mitigate bias in AI-enabled healthcare products and their use,

particularly where such bias may result in unfair or discriminatory outcomes for patients or population groups.

11.3.2 Measures to promote fairness shall be integrated throughout the product lifecycle, including data selection, algorithm development, validation, deployment, and post-market monitoring.

11.3.3 Ethical use of AI and robotics systems shall be guided by principles of beneficence, non-maleficence, equity, accountability, and respect for human dignity.

11.4 Data Protection and Patient Privacy

11.4.1 Personal data and health information processed by AI-enabled or robotics-enabled healthcare systems shall be protected against unauthorized access, disclosure, alteration, or loss.

11.4.2 Data collection, storage, processing, and sharing shall be limited to what is necessary for the intended medical purpose and shall comply with applicable data protection and privacy laws and regulations in force in Bangladesh.

11.4.3 Where data are used for secondary purposes such as system improvement, validation, or research, appropriate safeguards, anonymization or pseudonymization measures, and ethical approvals shall be applied, as required.

11.4.4 Data localization requirements specified under Section 8.5 shall be considered an essential component of patient privacy, national data sovereignty, and regulatory oversight.

11.5 Accountability and Patient Rights

11.5.1 The use of AI or robotic systems shall not diminish the professional responsibility and accountability of healthcare practitioners involved in patient care.

11.5.2 Patients shall retain the right to seek clarification regarding decisions or outcomes influenced by AI or robotic systems and to raise concerns or complaints through established institutional or regulatory mechanisms.

11.5.3 Responsible entities shall establish procedures to address patient grievances related to the use of AI or robotics in healthcare, including investigation and corrective actions where appropriate.

12. Institutional and Governance Framework

12.1 Regulatory Authority

12.1.1 The DGDA shall serve as the primary regulatory authority responsible for the oversight, regulation, approval, monitoring, and enforcement of requirements relating to Artificial Intelligence–enabled and robotics-enabled healthcare products in Bangladesh.

12.1.2 DGDA shall exercise its regulatory functions across the full product lifecycle, including pre-market evaluation, market authorization, post-market surveillance, inspection, and enforcement, in accordance with applicable laws, rules, and guidelines.

12.1.3 In carrying out its mandate under these Guidelines, DGDA may issue directives, circulars, technical guidance documents, or supplementary requirements as deemed necessary in the interest of patient safety and public health.

12.2 Multidisciplinary Technical Review Committee

12.2.1 DGDA may constitute a task force and/or multidisciplinary technical review committees to support the regulatory evaluation of AI-enabled and robotics-enabled healthcare products through an expedited process.

12.2.2 Such committees may include experts in medicine, biomedical engineering, clinicians, ethics, law, and health systems, as deemed appropriate for the nature and risk of the product under review.

12.2.3 The technical review committee shall provide expert advice to DGDA on matters including, but not limited to, product classification, clinical evaluation, risk management, ethical considerations, and post-market obligations.

12.2.4 The recommendations of the technical review committee shall be advisory in nature, and the final regulatory decision shall remain with DGDA.

12.3 Regulatory Sandbox and Conditional Approval Pathways

12.3.1 To facilitate responsible innovation while safeguarding patient safety, DGDA may establish a regulatory sandbox or controlled testing environment for selected AI-enabled or robotics-enabled healthcare products.

12.3.2 Products admitted to a regulatory sandbox may be permitted to operate under a defined scope, duration, and conditions, including limitations on patient population, clinical setting, functionality, and data use.

12.3.3 DGDA may grant conditional or staged approvals, subject to specified performance, safety, monitoring, or reporting requirements, where sufficient evidence exists to support controlled use but additional real-world data are required.

12.3.4 Continuation, expansion, modification, or withdrawal of sandbox participation or conditional approval shall be determined by DGDA based on ongoing performance data, risk assessment, and compliance with regulatory conditions.

12.4 Capacity Building and Institutional Readiness

12.4.1 DGDA shall promote and support capacity-building initiatives to strengthen regulatory competence in the assessment, inspection, and oversight of AI-enabled and robotics-enabled healthcare technologies.

12.4.2 Such initiatives may include specialized training programs, technical workshops, international collaboration, and knowledge exchange for regulators, inspectors, and technical officers.

12.4.3 DGDA may collaborate with academic institutions, professional bodies, international regulatory agencies, and development partners to enhance institutional readiness and keep pace with technological advancements.

12.4.4 Continuous capacity building shall be recognized as an essential element of effective governance to ensure consistent, evidence-based, and timely regulatory decision-making.

12.4.5 For robotics-enabled healthcare product, specifically for robotic surgery, a comprehensive training network should be established by the Government of Bangladesh in collaboration with the manufacturing country.

13. Alignment with International Standards

These Guidelines are developed with due consideration to internationally recognized principles, regulatory frameworks, and technical standards, in order to promote regulatory harmonization, facilitate safe innovation, and ensure consistency with global best practices in the regulation of Artificial Intelligence–enabled and robotics-enabled healthcare products.

In particular, these Guidelines are aligned with relevant guidance issued by the World Health Organization (WHO) on ethics, governance, and the safe use of Artificial Intelligence in health, including principles relating to transparency, accountability, patient safety, equity, and human oversight.

These Guidelines further consider the International Medical Device Regulators Forum (IMDRF) framework for Software as a Medical Device (SaMD), including risk-based classification, clinical evaluation, lifecycle management, and post-market monitoring concepts applicable to AI-enabled medical software [9,10,11].

With respect to quality and risk management, these Guidelines are aligned with internationally recognized standards, including ISO 13485, which specifies requirements for quality management systems applicable to medical device manufacturers, and ISO 14971, which establishes a systematic process for the identification, evaluation, control, and monitoring of risks associated with medical devices throughout their lifecycle.

For medical device software, including AI-enabled software components, these Guidelines are aligned with IEC 62304, which defines lifecycle processes for the safe design, development, maintenance, and modification of medical device software.

In addition, for medical robotic systems, including robotically assisted surgical systems and rehabilitation or assistive robots, these Guidelines take into account relevant particular safety and performance standards, including—

(a) IEC 80601-2-77:2019, which specifies particular requirements for the basic safety and essential performance of robotically assisted surgical equipment; and

(b) IEC 80601-2-78:2019, which specifies particular requirements for the basic safety and essential performance of medical robots intended for rehabilitation, assessment, compensation, or alleviation.

Conformity with the above international guidelines and standards, or their latest revisions, may be used by applicants and responsible entities to demonstrate compliance with relevant requirements of these Guidelines, subject to acceptance by DGDA.

Nothing in this section shall be construed as limiting the authority of the DGDA to require additional standards, evidence, or controls where necessary in the interest of patient safety, public health, or national regulatory priorities.

14. Conclusion and Way Forward

The proposed Artificial Intelligence and Robotics in Healthcare Guideline constitutes a significant and timely advancement toward establishing a robust, future-ready regulatory framework for healthcare technologies in Bangladesh. By adopting a risk-based, lifecycle-oriented, and ethically grounded approach, the Guideline provides a structured mechanism to address the unique safety, performance, and governance challenges posed by AI-enabled software and medical robotic systems across their entire lifecycle, from design and development through deployment and post-market use.

Through the implementation of these regulatory principles, Bangladesh can strengthen patient safety, clinical effectiveness, and public trust, while simultaneously fostering an enabling environment for responsible innovation, local research and development, and domestic manufacturing of advanced healthcare technologies. The Guideline is designed to balance regulatory oversight with technological flexibility, thereby supporting the safe introduction of adaptive and data-driven systems without imposing unnecessary barriers to innovation. Furthermore, the Guideline establishes a foundation for institutional capacity building, including the development of technical expertise within regulatory authorities, healthcare institutions, and inspection bodies, as well as the promotion of standardized practices for manufacturers, developers, and healthcare providers. It also creates opportunities for regulatory harmonization and international collaboration, facilitating alignment with global standards and enabling Bangladeshi manufacturers and innovators to participate more effectively in regional and international markets.

This Guideline is intended to serve as a foundational regulatory instrument, upon which future rules, directives, and sector-specific requirements may be developed in response to evolving technologies, clinical practices, and public health needs. As such, it represents an essential step toward strengthening Bangladesh's healthcare regulatory ecosystem and ensuring the safe, ethical, and effective integration of Artificial Intelligence and robotics into the national healthcare system.

15. References

1. Registration Guidelines for Medical Devices, Bangladesh 2015.
2. Artificial intelligent in healthcare guidelines, 2021, Singapore.
3. Regulatory guidelines for software medical devices – A life cycle approach, 2024, Singapore.
4. ISO 13485:2016 Medical devices — Quality management systems,
5. ISO 14971:2019 Medical devices — Application of risk management to medical devices
6. IEC 62304:2006 Medical device software — Software life cycle processes.

7. IEC 80601-2-77:2019: Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment
8. IEC 80601-2-78:2019 Medical electrical equipment Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
9. IMDRF, Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices, 31 October 2018.
10. IMDRF, Software as a Medical Device (SaMD): Clinical Evaluation, 21 September 2017.
11. IMDRF, Software as a Medical Device (SaMD): Application of Quality Management System, 2 October 2015.

Annex 1: Compliance Checklists for Artificial Intelligence

Guideline on the Regulation of Artificial Intelligence in Healthcare, Bangladesh

Use these checklists as annexes for national guideline implementation, procurement evaluation, pre-market submission screening, commissioning, and post-market compliance audits. Items may be marked as Not Applicable (NA) with justification, based on intended use and risk class.

Checklist 1: Artificial Intelligence-Enabled Healthcare Products (AI-MD / SaMD / SiMD)

Applies to AI-enabled software used for diagnosis, triage, monitoring, clinical decision support, treatment planning, therapy support, and other medical purposes, including adaptive or continuously learning systems.

No.	Requirement	Evidence / Deliverable	Responsibility	Verify (Yes/No/NA)	Remarks
1	Clearly state intended medical purpose, target population, intended users, clinical setting, and workflow point(s) of use.	Intended Use Statement; clinical workflow diagram; limitations and contraindications.	Manufacturer/ Developer		
2	Declare risk class and rationale, considering clinical impact and degree of autonomy and human oversight.	Classification rationale; autonomy description; human oversight plan.	Manufacturer/ Developer; DGDA review		
3	Provide device/software identification and versioning: name, unique identifier, software version, model version, release date.	Labeling/IFU; version history; configuration item list.	Manufacturer/ Developer		

4	Define input requirements and output types, including expected ranges and confidence or uncertainty indicators (where relevant).	Input specification; output specification; user manual.	Manufacturer/ Developer		
5	Document lawful basis for data access, consent or ethics approvals (where applicable), and data protection safeguards.	Data governance file; IRB or ethics approval; consent templates; de-identification approach.	Manufacturer/ Developer; Healthcare Institution		
6	Provide data provenance, traceability, and version control for training, validation, and test datasets.	Data provenance log; dataset versioning and audit trail; data lineage diagram.	Manufacturer/ Developer		
7	Demonstrate dataset representativeness for Bangladesh or intended deployment population (or justify limitations).	Dataset summary tables; demographic and clinical distribution; gap analysis and mitigation.	Manufacturer/ Developer		
8	Assess and mitigate bias and performance disparities across relevant subgroups (age, sex, comorbidity, site, device type).	Bias assessment report; subgroup performance metrics; mitigation actions.	Manufacturer/ Developer		
9	Describe annotation methods, label quality controls, and inter-rater reliability (if labeled data).	Annotation protocol; QA report; inter-rater agreement statistics.	Manufacturer/ Developer		

10	Define data quality checks (missingness, noise, artifacts) and robustness to input variability.	Data quality SOPs; robustness testing report.	Manufacturer/ Developer		
11	Document model type, architecture summary, training approach, and hyperparameter governance (at an appropriate level).	Model development report; training pipeline description; reproducibility plan.	Manufacturer/ Developer		
12	Demonstrate analytical validation: accuracy and robustness under expected use conditions.	Analytical validation report; test protocols; performance metrics.	Manufacturer/ Developer		
13	Demonstrate external validation (independent dataset or site) where risk level and intended use require it.	External validation report; site description; results summary.	Manufacturer/ Developer		
14	Define clinically meaningful performance thresholds and acceptance criteria aligned to intended use and current standard of care.	Performance claim table; acceptance criteria justification; comparator definition.	Manufacturer/ Developer; Clinical owner		
15	Document failure modes, performance boundaries, and known limitations, and communicate them in labeling.	Hazard analysis; user training materials.	Manufacturer/ Developer		

16	Confirm software verification and validation is proportional to software safety class and risk classification.	IEC 62304-aligned V&V plan; traceability matrix; test reports.	Manufacturer/ Developer		
17	Provide clinical validation evidence appropriate to the medical claim (retrospective, prospective, or clinical study).	Clinical evaluation report; study protocol; statistical analysis; results.	Manufacturer/ Developer; Healthcare Institution (if trial)		
18	Ensure explainability or interpretability measures are provided when outputs influence clinical decisions, and specify what they do and do not mean.	Explainability documentation; user guidance; examples and warnings.	Manufacturer/ Developer		
19	Define human oversight requirements: who reviews outputs, when escalation occurs, and how disagreements are handled.	Human-in-the-loop workflow; SOP; escalation protocol.	Healthcare Institution; Manufacturer guidance		
20	Operate under a Quality Management System for the full lifecycle (design through post-market).	ISO 13485 certificate or equivalent QMS evidence; quality manual.	Manufacturer/ Developer		
21	Perform and maintain risk management per ISO 14971, including AI hazards such as automation bias and dataset shift.	Risk management file; hazard analysis; risk control verification evidence.	Manufacturer/ Developer		
22	Maintain traceability between requirements, risks, design choices, test cases, and released versions.	Traceability matrix; design history file; change records.	Manufacturer/ Developer		

23	Define supplier and third-party software control, including open source components and an SBOM.	Supplier qualification records; SBOM; license compliance records.	Manufacturer/ Developer		
24	Conduct cybersecurity risk assessment and threat modeling proportional to connectivity and clinical risk.	Security risk assessment; threat model; security architecture overview.	Manufacturer/ Developer; Healthcare IT		
25	Implement secure design controls: authentication, authorization, encryption, secure logging, and secure update mechanism.	Security controls checklist; penetration test summary; secure update SOP.	Manufacturer/ Developer		
26	Provide customer security documentation: deployment hardening guide, network requirements, account management, logging.	Security deployment guide; configuration guidance; log export instructions.	Manufacturer/ Developer		
27	Define vulnerability disclosure, patch timelines, and incident response procedures.	Vulnerability handling policy; patch management plan; contact points.	Manufacturer/ Developer		
28	Ensure patient privacy controls: minimization, retention limits, access controls, and secure deletion.	Privacy impact assessment; data retention policy; access control policy.	Manufacturer/ Developer; Healthcare Institution		
29	Define implementation plan: integration with clinical workflow, EHR or PACS (if relevant), and contingency plan for downtime.	Implementation plan; interface specification; fallback workflow SOP.	Healthcare Institution; Manufacturer		

30	Conduct user training and competency assessment for intended users, including limitations and safe-use scenarios.	Training curriculum; competency assessment records; refresher plan.	Healthcare Institution; Manufacturer		
31	Establish local baseline performance at deployment and monitor drift and data shift over time.	Deployment baseline report; drift monitoring plan; audit schedule.	Healthcare Institution; Manufacturer		
32	Define post-market surveillance plan, including real-world performance monitoring and adverse event reporting.	PMS plan; vigilance SOP; reporting forms and timelines.	Manufacturer/ Developer; Healthcare Institution		
33	Define algorithm change management: notification triggers, approval requirements, and re-validation requirements.	Change management SOP; re-validation plan; regulatory communication plan.	Manufacturer/ Developer; DGDA review		
34	For continuously learning systems, define learning boundaries, update frequency, governance, and periodic review mechanism.	Continuous learning control plan; model update reports; periodic review records.	Manufacturer/ Developer; DGDA review		

Annex 2: Compliance Checklists for Medical Robotics

Guideline on the Regulation of Medical Robotics in Healthcare, Bangladesh

Use these checklists as annexes for national guideline implementation, procurement evaluation, pre-market submission screening, commissioning, and post-market compliance audits. Items may be marked as Not Applicable (NA) with justification, based on intended use and risk class.

For the registration of the surgical robots, this checklist needs to be submitted to DGDA for all the new facility/entity/branch.

Checklist 2: Medical Robotics Systems (Surgical, Diagnostic or Navigation, Rehabilitation, Assistive)

Applies to medical robots and robotic systems used in healthcare, including robotically assisted surgical systems, rehabilitation robots, and other robots that physically interact with patients or impact clinical decision-making.

No.	Requirement	Evidence / Deliverable	Responsibility	Verify (Yes/No/NA)	Remarks
1	State intended medical purpose, clinical workflow, target users, and operating environments (OR, ICU, rehab clinic, home).	Intended Use Statement; workflow diagram; limitations and contraindications.	Manufacturer/ Importer		
2	Provide full system configuration (robot, console, patient-side unit, accessories, instruments, software versions).	System description; configuration list; versioning records.	Manufacturer/ Importer		

3	Declare risk class and autonomy level, with defined human oversight and intervention points.	Classification rationale; autonomy description; human oversight plan.	Manufacturer/ Importer; DGDA review		
4	Provide medical electrical safety evidence (IEC 60601-1 or equivalent) for the robot and its applicable parts.	Electrical safety test report; protective earth continuity evidence.	Manufacturer/ Importer		
5	Provide EMC evidence (IEC 60601-1-2 or equivalent) and confirm safe operation in intended environments.	EMC test report; immunity and emissions summary; coexistence considerations.	Manufacturer/ Importer		
6	Provide usability engineering evidence (IEC 62366-1) for operator interface, alarms, and emergency actions.	Usability engineering file; summative evaluation results.	Manufacturer/ Importer		
7	Provide software lifecycle evidence (IEC 62304) for robot control software and connected software components.	Software lifecycle documentation; V&V plan and test reports.	Manufacturer/ Importer		
8	Provide risk management evidence (ISO 14971), including hazards from motion, force, collision, and incorrect information.	Risk management file; hazard analysis; risk controls verification.	Manufacturer/ Importer		

9	Provide cybersecurity controls proportionate to connectivity and risk (secure updates, access control, logging).	Cybersecurity assessment; hardening guide; patch policy.	Manufacturer/ Importer; Healthcare IT		
10	For robotically assisted surgical systems, provide compliance evidence to IEC 80601-2-77 (as applicable).	IEC 80601-2-77 conformity evidence; test summary; essential performance claims.	Manufacturer/ Importer		
11	For rehabilitation robots that physically interact with patients, provide compliance evidence to IEC 80601-2-78 (as applicable).	IEC 80601-2-78 conformity evidence; test summary; essential performance claims.	Manufacturer/ Importer		
12	Define motion limits, speed limits, and force or torque limits, and verify under normal and fault conditions.	Motion and force specification; verification test reports; fault condition results.	Manufacturer/ Importer		
13	Demonstrate safe-stop behavior: emergency stop, protective stop, and controlled stop as applicable.	E-stop and protective stop test reports; recovery procedure documentation.	Manufacturer/ Importer; Healthcare Institution		
14	Assess collision and pinch or crush hazards in all operating zones and provide engineered mitigations.	Mechanical hazard analysis; guarding and interlock evidence; validation report.	Manufacturer/ Importer		

15	Verify stability, transport safety, and anchoring or locking mechanisms (if mobile or floor-mounted).	Stability test; transport SOP; installation drawings.	Manufacturer/ Importer; Healthcare Institution		
16	Document all interfaces and dependencies (imaging, navigation, energy devices, network, external sensors).	Interface control document; integration diagram; compatibility list.	Manufacturer/ Importer		
17	Verify safe coexistence with other clinical equipment, including electromagnetic interference risk and mitigation.	Coexistence testing summary; EMC risk analysis; clinical environment checklist.	Manufacturer/ Importer; Healthcare Institution		
18	Define data logging, audit trail, and export mechanisms for safety events and service diagnostics.	Logging specification; audit trail description; export procedure.	Manufacturer/ Importer		
19	Provide sterile field workflow: draping method, sterile accessories, and sterile processing instructions (if reusable).	IFU; reprocessing validation; sterile barrier evidence.	Manufacturer/ Importer; Hospital CSSD		
20	Provide release-of-patient procedure and drills for power loss, fault, or instrument jam.	Patient release SOP; simulation or drill checklist; recovery procedures.	Manufacturer/ Importer; Healthcare Institution		

21	Provide instrument lifecycle controls: usage limits, inspection criteria, and traceability.	Instrument tracking requirements; lifecycle limits; maintenance logs.	Manufacturer/ Importer; Healthcare Institution		
22	Define patient fitment, alignment checks, skin safety controls, and stopping rules for pain or abnormal vitals (rehab/assistive).	Patient selection and fitment guide; session SOP; stopping rules.	Manufacturer/ Importer; Healthcare Institution		
23	Define fall risk mitigation (harness, support, spotter requirements) and verify safe behavior during loss of balance (rehab/assistive).	Fall risk management plan; test and drill records; training materials.	Healthcare Institution; Manufacturer guidance		
24	Provide Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) protocols with pass or fail criteria.	FAT and SAT protocols; executed test reports; deviations and CAPA.	Manufacturer/ Importer; Healthcare Institution		
25	Confirm calibration and periodic verification requirements, including tools needed and intervals.	Calibration SOP; schedules; certificates; checklists.	Manufacturer/ Importer; Biomedical Engineering		
26	Provide preventive maintenance schedule, spare parts, service manuals, and service response times.	Maintenance plan; spare parts list; SLA; service manuals.	Manufacturer/ Importer		

27	Ensure operator and maintenance staff training and credentialing, including emergency actions and troubleshooting.	Training curriculum; competency records; refresher plan.	Healthcare Institution; Manufacturer		
28	List of trained personnel	Trained personnel list needs to be updated during new registration	Healthcare Institution; Manufacturer		
29	Define software update governance and rollback, including who authorizes updates and how downtime is handled.	Update SOP; rollback procedure; change impact assessment template.	Healthcare Institution; Manufacturer		
30	Establish post-market surveillance plan and reporting workflow for adverse events, malfunctions, and cybersecurity incidents.	PMS plan; vigilance SOP; reporting forms; timelines.	Manufacturer/ Importer; Healthcare Institution		
30	Monitor real-world performance and safety signals, including trend analysis of alarms, near misses, and component failures.	Periodic safety review reports; log analytics; corrective action records.	Healthcare Institution; Manufacturer		

31	Maintain change management for hardware and software modifications, with re-validation and DGDA notification where required.	Change records; re-validation evidence; regulatory correspondence.	Manufacturer/ Importer; DGDA review		

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