

Bangladesh — Gap Analysis Report

13 Regulatory Tiles | Medical Devices Regulatory Intelligence

JURISDICTION	PRIMARY FRAMEWORK	AUTHORITY
Bangladesh (BD)	Medical Device Rules, 2022 (SRO No. 91-AIN/2022)	DGDA (Directorate General of Drug Administration)
REPORT DATE	PREPARED BY	
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QUICK REFERENCE SUMMARY

#	Tile	Status	Primary Legal Basis	Key Requirement
1	Classification Rules	Regulated	Medical Device Rules 2022, Rule 4 & Schedule I	4-class risk-based system (A, B, C, D); IMDRF-aligned
2	Obligations	Regulated	Medical Device Rules 2022, Rules 5–30	Registration, labeling, QMS, PMS, vigilance, AR
3	Notified Body	Partial	Medical Device Rules 2022, Rules 14–16	No EU-style NB system; DGDA is sole CA; CB recognition possible
4	Battery Requirements	Partial	No dedicated MD battery regulation; IEC 62133 referenced	Safety standards apply; UN 38.3 for transport
5	Shelf-Life Requirements	Regulated	Medical Device Rules 2022, Rule 19 & Schedule III (Labeling)	Mandatory expiry date on label; manufacturer validates shelf life
6	REACH	Not Applicable	No national REACH equivalent	EU REACH does not apply; no Bangladesh-specific REACH law
7	RoHS	Not Applicable	No national RoHS equivalent	No Bangladesh-specific RoHS restriction; EU RoHS applies for EU export
8	Change Control	Regulated	Medical Device Rules 2022, Rule 25	Post-approval changes require DGDA variation application
9	OTC Requirements	Partial	Medical Device Rules 2022, Rules 19–21	Class A/B generally OTC; labeling must include Bengali instructions

#	Tile	Status	Primary Legal Basis	Key Requirement
10	Export Certificates	Regulated	Medical Device Rules 2022, Rule 29; Drugs Act 1940	DGDA issues Free Sale Certificate / Certificate for Export
11	Transportation & Storage	Partial	Medical Device Rules 2022, Rule 19; Schedule III	Conditions stated on label; cold chain for temperature-sensitive devices
12	Waste Management	Partial	Medical Waste Management Rules 2008; Environment Conservation Act 1995	Bio-medical waste rules apply; no WEEE-specific MD disposal framework
13	AI Medical Device	No Regulation	No specific AI/SaMD regulation published	Covered under general software provisions of MDR 2022; AI-specific guidance pending

1 Classification Rules

DEFINITION

Bangladesh classifies medical devices into four risk classes (A, B, C, D) using a risk-based approach aligned with the IMDRF/ASEAN framework. Class A is lowest risk and Class D is highest risk. Classification is based on intended use, duration of contact, degree of invasiveness, and whether the device delivers energy or incorporates a substance.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 4, Schedule I (Classification Rules)	www.dgda.gov.bd
Drugs Act, 1940 (as amended)	Foundational enabling legislation	www.dgda.gov.bd
IMDRF/GRRP WG/N47 FINAL:2018	Principles of Medical Device Classification (international reference adopted)	www.imdrf.org

CLASSIFICATION CRITERIA

Class	Risk Level	Examples	Conformity Pathway
Class A	Lowest risk / Non-invasive	Bandages, tongue depressors, wheelchairs	Self-declaration / simplified registration
Class B	Low-medium risk	Hypodermic needles, suction devices, blood pressure monitors	DGDA registration with technical file
Class C	Medium-high risk	Ventilators, bone fixation plates, infusion pumps	DGDA registration + QMS (ISO 13485) + clinical evidence
Class D	Highest risk	Implantable cardiac defibrillators, HIV test kits, coronary stents	DGDA full approval + QMS + clinical data + third-party evidence

CLASSIFICATION RULES SUMMARY (SCHEDULE I)

The classification rules in Schedule I of the Medical Device Rules 2022 include:

- **Rule 1 — Non-invasive devices:** Generally Class A unless they interact with injured skin, contact blood/tissue fluids, or modify fluid compositions (Class B/C).
- **Rule 2 — Invasive devices:** Body orifice contact: Class A (short-term use), Class B (long-term), Class C/D (surgically invasive or implantable).
- **Rule 3 — Surgically invasive devices:** Short-term Class B; long-term implantable devices Class C or D.
- **Rule 4 — Active devices:** Active therapeutic devices Class B; active devices delivering energy in potentially hazardous manner Class C; active implantable devices Class D.
- **Rule 5 — Special rules:** Devices incorporating a medicinal substance, devices using human or animal tissues, devices for contraception or sterilization upgraded to Class C or D.
- **Rule 6 — IVD devices:** Class D (high-risk: HIV, blood grouping); Class C (self-testing, companion diagnostics); Class B (general lab use); Class A (general purpose lab instruments).

ADDITIONAL INFORMATION

Where a device falls into multiple classes, the higher class applies. DGDA may reclassify a device based on new safety information. Combination products (device + drug) are regulated based on the primary mode of action. The classification list is periodically updated by DGDA gazette notification.

DEFINITION

Obligations under the Medical Device Rules 2022 cover the full product lifecycle for manufacturers, importers, distributors, and authorized representatives. Key obligations include device registration, quality management, labeling, post-market surveillance, adverse event reporting, and appointment of a local authorized representative (AR) for foreign manufacturers.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rules 5–30 (full obligations framework)	www.dgda.gov.bd
Drug Control Ordinance, 1982	Import and distribution licensing	www.dgda.gov.bd
Drugs Act, 1940	Foundational licensing provisions	www.dgda.gov.bd

KEY OBLIGATIONS BY ACTOR

Actor	Obligations
Foreign Manufacturer	• Appoint a Bangladesh-registered Authorized Representative (AR) • Maintain ISO 13485 QMS (Class C and D mandatory) • Prepare and maintain technical documentation • Submit clinical evidence / performance evaluation data • Ensure labeling in English and Bengali • Report serious adverse events to DGDA within 30 days (Class C/D)
Authorized Representative (AR)	• Must be a Bangladesh-registered legal entity • Acts as the regulatory contact for DGDA on behalf of foreign manufacturer • Responsible for registration applications and updates • Must hold an Import License from DGDA
Importer / Distributor	• Must obtain Drug Import License from DGDA • May only import registered devices • Maintain traceability records • Recall obligations in case of safety issues
Local Manufacturer	• Must obtain Manufacturing License from DGDA • Maintain QMS per ISO 13485 (Class C/D) • Factory inspection by DGDA required • Submit full technical dossier for registration

REGISTRATION REQUIREMENTS

- **Class A:** Simplified notification / listing with DGDA; basic technical documentation

- **Class B:** Full registration application; technical file; labeling review
- **Class C:** Full registration; ISO 13485 certificate; clinical evidence; QMS audit possible
- **Class D:** Full registration; pre-market approval; clinical data; third-party certification (FDA/CE/TGA accepted as supporting evidence); on-site inspection possible

Registration validity: typically 5 years, renewable before expiry.

POST-MARKET OBLIGATIONS

- Post-market surveillance plan required for Class C and D devices
- Periodic Safety Update Reports (PSURs) for high-risk devices
- Adverse event reporting: serious incidents within 30 days; imminent hazards within 48 hours
- Field safety corrective actions (FSCA) must be reported to DGDA
- Recall procedures: DGDA-directed or voluntary; documented within MDR 2022 Rules 26–28

DEFINITION

Bangladesh does not operate a European-style Notified Body (NB) system. The Directorate General of Drug Administration (DGDA) serves as the sole competent authority responsible for market authorization, conformity assessment, inspection, and regulatory oversight of medical devices. There is no separate third-party conformity assessment body formally designated as a "Notified Body" under Bangladeshi law.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rules 14–16 (Conformity Assessment)	www.dgda.gov.bd
Drug Control Ordinance, 1982	DGDA establishment and powers	www.dgda.gov.bd
Bangladesh Accreditation Board (BAB)	Accreditation of testing laboratories	www.bab.gov.bd

COMPETENT AUTHORITY: DGDA

- **Full name:** Directorate General of Drug Administration
- **Ministry:** Ministry of Health and Family Welfare
- **Address:** 32 Manik Mia Avenue, Dhaka 1215, Bangladesh
- **Website:** www.dgda.gov.bd
- **Role:** Market authorization; GMP/QMS inspections; vigilance; import licensing; post-market surveillance

THIRD-PARTY TESTING AND RECOGNITION

For Class C and D devices, DGDA may accept conformity certificates from recognized international bodies as supporting evidence:

- US FDA 510(k) clearance or PMA approval
- EU CE marking under EU MDR 2017/745 or EU IVDR 2017/746
- Australian TGA registration
- Japanese PMDA approval

Such certificates do not replace DGDA registration but may expedite the technical review process. Testing may be required at Bangladesh Standards and Testing Institution (BSTI) or BAB-accredited laboratories for specific product types.

GAP NOTE

⚠ PARTIAL COVERAGE

Bangladesh has no formal Notified Body designation system. The concept of an independent conformity assessment body issuing certificates (as in the EU) is not present. Manufacturers relying on an EU CE certificate will still need to go through DGDA's full registration process separately.

DEFINITION

Bangladesh does not have a dedicated regulation specifically governing batteries in medical devices. Battery safety requirements are addressed indirectly through the general safety and performance requirements of the Medical Device Rules 2022, applicable international standards referenced by DGDA, and transportation regulations (UN 38.3 for lithium batteries).

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 11 – Essential Principles / General Safety and Performance Requirements	www.dgda.gov.bd
IEC 62133-1 / IEC 62133-2	Safety requirements for portable sealed secondary cells and batteries	www.iec.ch
UN Manual of Tests and Criteria — Section 38.3	Lithium battery transport testing requirements	unece.org
IEC 60086 series	Primary batteries — specifications and safety	www.iec.ch
BSTI Standards	Bangladesh Standards and Testing Institution standards where applicable	www.bsti.gov.bd

KEY REQUIREMENTS

- Medical devices with integral or rechargeable batteries must comply with the essential safety and performance principles under Rule 11 of the Medical Device Rules 2022
- Devices must be designed to minimize risks of overheating, fire, explosion, or electrical hazards associated with batteries
- Battery type, voltage, and replacement instructions must be included on the label or in the instructions for use (IFU)
- Lithium batteries (rechargeable and non-rechargeable) must pass UN 38.3 testing for air transport
- IEC 62133 compliance is expected for rechargeable lithium-ion and nickel-metal hydride cells used in portable medical devices
- Battery disposal instructions should be included in the IFU in accordance with applicable waste management guidance

GAP NOTE

⚠ PARTIAL COVERAGE

No dedicated Bangladesh Medical Device Battery Regulation exists as of 2025. Requirements are extrapolated from general essential principles and international standards. Manufacturers should declare compliance with applicable IEC standards in their technical documentation submitted to DGDA. A specific battery regulation for medical devices has not been gazetted.

DEFINITION

The shelf life of a medical device is the period during which a device, when stored under specified conditions, maintains its intended performance and safety characteristics. Bangladesh requires manufacturers to determine, validate, and declare the shelf life of their devices, which must appear on the product label and packaging.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 19 – Labeling; Schedule III (Labeling Requirements)	www.dgda.gov.bd
Medical Device Rules, 2022	Rule 11 – Essential Principles (device performance over lifetime)	www.dgda.gov.bd
ISO 11607	Packaging for terminally sterilized medical devices (sterile barrier system shelf life)	www.iso.org
ISO 13485:2016	Clause 7.5.11 – Preservation of product, including shelf-life validation	www.iso.org

LABELING REQUIREMENTS (SCHEDULE III)

The following shelf-life-related information is mandatory on the label of a medical device marketed in Bangladesh:

- Expiry date (or "use by" date): must be expressed as DD/MM/YYYY or at minimum MM/YYYY
- Date of manufacture: required on the primary label
- Storage conditions (e.g., "Store below 25°C, away from direct sunlight")
- For sterile devices: sterile barrier system shelf life must be validated and stated
- Single-use designation with prohibition on reuse where applicable

SHELF-LIFE VALIDATION

- Manufacturers must conduct real-time and/or accelerated aging studies to validate the claimed shelf life
- Studies must be documented in the technical dossier submitted to DGDA
- For sterile devices: sterile barrier integrity testing per ISO 11607-1 is required
- For implantable devices (Class D): extended shelf-life validation (typically up to 5–10 years) with documented rationale
- Shelf-life claims must be supported by stability data; DGDA may request this during technical review

DEFINITION

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a European Union regulation (EC No 1907/2006). Bangladesh is not a member of the EU and has no equivalent national legislation to REACH. Therefore, EU REACH obligations (Substances of Very High Concern — SVHC, authorization, restriction) do not apply to devices placed solely on the Bangladeshi market.

LEGAL BASIS

Instrument	Reference	URL
EU REACH Regulation (EC) No 1907/2006	Applies only to EU market — NOT applicable in Bangladesh	echa.europa.eu
Bangladesh Environment Conservation Act, 1995 (Act No. 1 of 1995)	General environmental protection; some hazardous substance controls	moef.gov.bd
Hazardous Waste and Ship Breaking Waste Management Rules, 2011	Hazardous chemicals in industrial waste — limited applicability to MD	moef.gov.bd

STATUS IN BANGLADESH

- Bangladesh has no national chemical registration or REACH-equivalent regulation
- The Bangladesh Environment Conservation Act 1995 provides general hazardous substance controls but does not impose SVHC identification or restriction requirements comparable to REACH
- Manufacturers exporting devices to both Bangladesh and the EU must comply with EU REACH for the EU market; REACH compliance is not a condition of DGDA registration
- Some multinational manufacturers voluntarily maintain REACH-compliant supply chains, but this is not a legal requirement for the Bangladesh market

PRACTICAL GUIDANCE

NOTE FOR MANUFACTURERS

If your device contains substances that would be SVHC-restricted under EU REACH, this does not automatically affect Bangladesh registration. However, manufacturers should document material composition in their technical dossier as DGDA may query chemical composition for Class C/D devices, particularly implantables. Compliance with RoHS and REACH for EU exports remains the manufacturer's responsibility under EU law.

DEFINITION

RoHS (Restriction of Hazardous Substances) Directive 2011/65/EU restricts the use of specific hazardous materials (lead, mercury, cadmium, hexavalent chromium, PBBs, PBDEs, and four phthalates) in electrical and electronic equipment, including medical devices. Bangladesh has no national equivalent to RoHS and does not require RoHS compliance for devices placed on the Bangladesh market.

LEGAL BASIS

Instrument	Reference	URL
EU RoHS Directive 2011/65/EU (recast)	Restricted substances list — applies only to EU market	ec.europa.eu
Bangladesh Environment Conservation Act, 1995	General hazardous substance framework; does not specifically restrict RoHS substances in electronics	moef.gov.bd
Bangladesh Electrical Safety Rules (draft)	General electrical safety; not specifically RoHS-equivalent	—

STATUS IN BANGLADESH

- No RoHS-equivalent national regulation exists in Bangladesh as of 2025
- Electrical and electronic medical devices are regulated under the Medical Device Rules 2022 for safety and performance, but specific hazardous substance restrictions comparable to RoHS are not imposed
- Bangladesh has not enacted an E-waste / WEEE law that includes RoHS-style substance restrictions
- Manufacturers who comply with RoHS for EU exports may note compliance on technical documentation, but this is voluntary for the Bangladesh market

PRACTICAL GUIDANCE

i NOTE FOR MANUFACTURERS

While RoHS is not legally required for Bangladesh registration, global manufacturers typically maintain RoHS compliance across all markets for supply chain efficiency and customer preference. DGDA does not request RoHS declarations as part of the registration dossier. No specific derogations or exemptions need to be claimed for Bangladesh.

DEFINITION

Change control requirements govern how post-approval changes to a registered medical device must be managed and communicated to DGDA. Changes that affect the safety, performance, or identity of a device may require a variation application (Type I or Type II) to be submitted to DGDA before implementation.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 25 – Variation to Registration	www.dgda.gov.bd
Medical Device Rules, 2022	Rule 26 – Transfer of Registration	www.dgda.gov.bd
ISO 13485:2016	Clause 4.1.6, 7.3.9 – Change management within QMS	www.iso.org

TYPES OF CHANGES AND REQUIREMENTS

Change Type	Classification	DGDA Action Required
Change of authorized representative or importer	Administrative	Type I variation — notification with supporting documentation
Labeling changes (editorial, address update)	Minor	Type I variation — file notification with revised label
Manufacturing site addition / change	Moderate	Type II variation — prior approval required; may trigger QMS audit
Design change affecting safety or performance	Significant	Type II variation — full technical documentation; clinical data may be needed
Intended use expansion	Major	New registration application required
Change in active ingredient / biological constituent	Major	New registration application required
Critical change affecting patient safety	Urgent Field Safety Action	Immediate FSCA notification within 48 hours; variation submitted concurrently

INTERNAL QMS CHANGE CONTROL

Under ISO 13485:2016 (mandatory for Class C and D), manufacturers must maintain a documented change control procedure covering:

- Risk assessment of proposed changes
- Determination of regulatory impact (reportable vs. non-reportable)
- Verification and validation of changes
- Update of design history file and technical documentation
- Communication to DGDA where required under Rule 25

DEFINITION

Over-the-Counter (OTC) medical devices are devices that may be purchased and used without a prescription or medical supervision. In Bangladesh, the distinction between prescription and OTC devices is based on device classification and intended use. Generally, Class A and low-risk Class B devices may be sold OTC, while Class C and D devices typically require healthcare professional involvement.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rules 19–21 – Labeling and Instructions for Use	www.dgda.gov.bd
Medical Device Rules, 2022	Rule 4 – Classification (basis for OTC eligibility)	www.dgda.gov.bd
Drugs Act, 1940	Distribution licensing framework	www.dgda.gov.bd

OTC ELIGIBILITY

Class	OTC Status	Notes
Class A	Generally OTC	Bandages, glucometers (for patient self-use), thermometers, hearing aids
Class B	OTC for self-test / patient-use devices	Blood pressure monitors, pregnancy tests, basic IVD kits
Class C	Professional use; not OTC unless specifically indicated	Infusion pumps, ventilators — require clinical setting
Class D	Prescription / professional only	Implantables, high-risk IVDs — require medical prescription/order

OTC LABELING REQUIREMENTS

- Instructions for use (IFU) must be in **both English and Bengali** for OTC devices sold to end consumers
- Adequate safety warnings and contraindications must be clearly stated
- Pictograms / symbols may supplement text but cannot replace Bengali-language instructions
- For self-test IVDs: step-by-step instructions in Bengali are mandatory
- Consumer-facing labels must include: device name, intended use, manufacturer, expiry date, storage conditions, and batch/lot number

GAP NOTE

⚠ PARTIAL COVERAGE

Bangladesh's Medical Device Rules 2022 do not define an explicit separate "OTC" category as a regulatory designation. OTC eligibility is inferred from classification and intended use. There is no equivalent to the US FDA OTC monograph system. DGDA may clarify OTC status on a case-by-case basis during registration review.

10 Export Certificates

DEFINITION

Export certificates (also called Free Sale Certificates or Certificates of Free Sale) are official DGDA documents confirming that a medical device is legally registered and marketed in Bangladesh. They are issued to Bangladeshi manufacturers or importers for the purpose of exporting devices to foreign markets that require proof of home-country approval.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 29 – Certificate for Export	www.dgda.gov.bd
Drugs Act, 1940	Section 12 – Export licensing framework	www.dgda.gov.bd
WHO Guidelines	WHO Guidance on Free Sale Certificates for Medical Products (referenced by DGDA)	www.who.int

TYPES OF EXPORT CERTIFICATES

Certificate Type	Description	Issued By
Certificate of Free Sale (CFS)	Confirms the device is freely sold on the Bangladesh market without restriction	DGDA
Certificate for Export (Non-registered devices)	For devices manufactured in Bangladesh solely for export (not marketed locally)	DGDA
Good Manufacturing Practice Certificate	Confirms manufacturer compliance with GMP standards	DGDA (after factory inspection)

APPLICATION REQUIREMENTS

- Application to DGDA with proof of current device registration
- Fees payable as per DGDA fee schedule
- Certificate issued per product per destination country (or multi-country)
- Validity: typically 1–2 years; renewable
- Apostille / legalization available for countries requiring official notarization
- DGDA certificates are recognized under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (applicable by analogy to medical devices)

DEFINITION

Transportation and storage requirements for medical devices in Bangladesh ensure that devices maintain their safety, integrity, and performance characteristics throughout the supply chain. Requirements are set through labeling obligations in the Medical Device Rules 2022, with additional guidance from international standards and DGDA guidance.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 19 – Labeling (storage / handling conditions); Schedule III	www.dgda.gov.bd
Medical Device Rules, 2022	Rule 11 – Essential Principles (device stability during transport)	www.dgda.gov.bd
IATA Dangerous Goods Regulations (DGR)	Air transport of hazardous materials including lithium batteries and biological substances	www.iata.org
UN 38.3	Lithium battery transport testing	unece.org
ISO 11135 / ISO 11137	Sterilization validation — relevant to sterile device transport packaging	www.iso.org
ASTM D4169	Performance testing of shipping containers and systems	www.astm.org

STORAGE LABELING REQUIREMENTS (SCHEDULE III)

- Temperature range: e.g., "Store between 2°C and 8°C" for cold-chain devices
- Humidity conditions: e.g., "Store in a dry place, relative humidity ≤ 60%"
- Light protection: e.g., "Keep away from direct sunlight"
- Handling precautions: e.g., "Fragile — Handle with care"; "Keep upright"
- Stacking/compression limits where applicable

COLD CHAIN REQUIREMENTS

- Temperature-sensitive devices (e.g., certain IVDs, biologically derived devices) require validated cold-chain transport from manufacturer to end user
- Cold-chain validation studies should be included in the technical dossier
- Distribution centers and importers must maintain cold-chain facilities verified by DGDA inspection for Class C/D cold-chain devices
- Temperature excursion protocols must be documented and available to DGDA on request

GAP NOTE

▲ PARTIAL COVERAGE

Bangladesh does not have a standalone Good Distribution Practice (GDP) guideline for medical devices equivalent to EU GDP guidelines (2013/C 343/01). Distribution and storage practices are regulated through DGDA import licensing conditions and general GMP requirements rather than a dedicated GDP framework.

DEFINITION

Waste management requirements for medical devices in Bangladesh address the disposal of bio-medical waste generated by healthcare facilities and the handling of used/end-of-life medical devices, particularly those that are sharps, single-use, or contain hazardous materials. Bangladesh does not have a WEEE (Waste Electrical and Electronic Equipment) specific framework for medical devices.

LEGAL BASIS

Instrument	Reference	URL
Medical Waste Management Rules, 2008	Management of clinical / bio-medical waste from healthcare facilities	moef.gov.bd
Bangladesh Environment Conservation Act, 1995 (Act No. 1 of 1995)	Environmental protection; hazardous waste controls	moef.gov.bd
Hazardous Waste and Ship Breaking Waste Management Rules, 2011	Disposal of hazardous industrial waste	moef.gov.bd
Bangladesh Environment Conservation Rules, 1997	Environmental standards including standards for solid waste disposal	moef.gov.bd
EU WEEE Directive 2012/19/EU	Reference only — not applicable in Bangladesh but relevant for EU-market compliance	ec.europa.eu

MEDICAL WASTE MANAGEMENT RULES 2008 — KEY CATEGORIES

Category	Examples	Disposal Method
Sharps waste	Needles, scalpels, lancets, broken glass	Puncture-resistant containers; incineration or sterilization before disposal
Infectious waste	Used dressings, blood-soaked materials, microbiological cultures	Autoclave / steam sterilization; then landfill or incineration
Pathological waste	Human tissue, body parts	Incineration; burial in approved facility
Pharmaceutical waste	Expired medicines, vaccines	Incineration at approved facilities; not in municipal waste
Chemical waste	Solvents, disinfectants, heavy metals from medical devices	Segregated disposal per Hazardous Waste Rules 2011
Electrical/Electronic waste (E-waste)	Used imaging equipment, monitors, electronic diagnostic devices	No dedicated WEEE framework; general solid waste disposal or recycler pickup

MANUFACTURER OBLIGATIONS

- Single-use devices: must be clearly labeled "Single Use Only" with a prohibition symbol (DO NOT REUSE) per Schedule III
- IFU must include disposal instructions appropriate for the device type and materials
- For devices containing mercury, lead, cadmium, or radioactive components: special disposal instructions required

- Importers and distributors are responsible for ensuring customers receive adequate disposal guidance

GAP NOTE

⚠ PARTIAL COVERAGE

Bangladesh does not have a WEEE-specific framework for electrical and electronic medical devices (e.g., MRI machines, CT scanners, infusion pumps). E-waste management relies on general environmental rules. An E-Waste Management Policy has been discussed at government level but had not been formally enacted as of 2025. Manufacturers of electrical medical devices should provide responsible disposal guidance in IFU based on best practice.

DEFINITION

AI-enabled medical devices (AI/ML-based Software as a Medical Device — SaMD) are medical devices that use artificial intelligence or machine learning algorithms to diagnose, monitor, treat, or predict medical conditions. As of 2025, Bangladesh does not have a specific regulatory framework for AI medical devices. AI-based medical devices are regulated under the general Medical Device Rules 2022 framework, classified by risk and intended use.

LEGAL BASIS

Instrument	Reference	URL
Medical Device Rules, 2022	Rule 4 – Classification (SaMD follows IVD/active device rules); Rule 11 – Essential Principles	www.dgda.gov.bd
IMDRF SaMD Framework (IMDRF/SaMD WG/N41FINAL:2017)	Software as a Medical Device: Clinical Evaluation (international reference)	www.imdrf.org
IEC 62304:2006 + AMD1:2015	Medical device software — software life cycle processes	www.iec.ch
IEC 62366-1:2015	Medical devices — usability engineering (relevant for AI interface design)	www.iec.ch
EU AI Act 2024/1689/EU	Reference only — not applicable in Bangladesh; governs EU market AI systems	eur-lex.europa.eu
US FDA AI/ML-Based SaMD Action Plan (2021)	International reference for AI SaMD regulatory principles	www.fda.gov

CURRENT REGULATORY STATUS

- **No AI-specific regulation:** DGDA has not published AI/ML-specific guidance for medical devices as of 2025
- **Classification:** AI-based SaMD is classified under the general classification rules based on intended use and risk. An AI diagnostic tool for detecting cancer would likely be Class C or D; a general wellness app would be Class A (if regulated at all)
- **Software lifecycle:** IEC 62304 compliance is expected in the technical dossier for software-based devices
- **Clinical evidence:** AI/ML-based devices require clinical performance evaluation data demonstrating algorithm accuracy, sensitivity, specificity, and safety
- **Continuous learning:** AI devices that update algorithms post-market (adaptive AI) would likely require a variation application under Rule 25 for each significant algorithm update affecting performance

RECOMMENDED INTERNATIONAL STANDARDS FOR AI SAMD IN BANGLADESH

Standard	Scope
IEC 62304:2006+A1:2015	Software lifecycle processes for medical device software
IEC 62366-1:2015	Usability engineering — application to SaMD/AI interfaces
ISO 14971:2019	Risk management for medical devices (including AI failure modes)
IMDRF/SaMD WG/N41FINAL:2017	Clinical Evaluation of SaMD

Standard	Scope
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ISO/IEC TR 24028:2020

AI trustworthiness — overview of ethical and technical concerns

GAP NOTE

⚠️ REGULATORY GAP — AI-SPECIFIC GUIDANCE ABSENT

Bangladesh has a significant gap in AI medical device regulation. No DGDA guidance document exists specifically addressing AI/ML algorithms, algorithmic transparency, bias testing, continuous learning, or the "Software as a Medical Device" concept. Manufacturers of AI medical devices should follow international best practices (FDA, EU MDR, IMDRF SaMD framework) and include comprehensive technical documentation in DGDA registration submissions. DGDA is expected to develop AI-specific guidance in alignment with IMDRF principles in future regulatory updates.