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DEPARTMENT OF BIOMEDICAL ENGINEERING
VI Semester
BIOMEDICAL DEVICE DESIGN
UNIT- I INTRODUCTION TO BIOMEDICAL DEVICE DESIGN AND CLINICAL NEED IDENTIFICATION

1.2 Medical Device Classification and Risk Categories:

➢ **Need for classification**

Medical devices differ enormously in the harm they can cause if they fail. A tongue depressor and an implantable defibrillator cannot be regulated in the same way. Classification groups devices by **risk** so that regulators can apply control in proportion to danger, and so that manufacturers know the evidence, quality system and documentation that they must provide.

- ❖ Ensures patient and user safety proportionate to risk.
- ❖ Avoids over-regulating simple products and under-regulating critical ones.
- ❖ Defines the conformity assessment route (self-declaration, audit, full premarket approval).
- ❖ Harmonises requirements across countries (IMDRF/GHTF model).
- ❖ Helps designers decide the level of design controls, testing and clinical evidence early in the project.

➢ **Factors that decide the risk class**

Table 1.6 Factors used to assign risk class

Factor	Question asked	Effect on class
Intended use	What medical purpose is claimed? Diagnosis, therapy, life support?	Life-support or critical diagnosis raises class
Invasiveness	Does it penetrate the body, orifice or skin?	Surgically invasive and implants rise
Duration of contact	Transient (<60 min), short term (<30 days) or long term (>30 days)?	Longer contact raises class
Active or passive	Does it depend on electrical or other energy source?	Active therapeutic devices rise
Body site	Heart, central circulatory system, central nervous system?	Contact with vital organs raises class

Factor	Question asked	Effect on class
Local vs systemic effect	Does it release energy or substances into the body?	Systemic delivery raises class
Software role	Does software drive treatment or diagnosis decisions?	Higher harm potential raises class

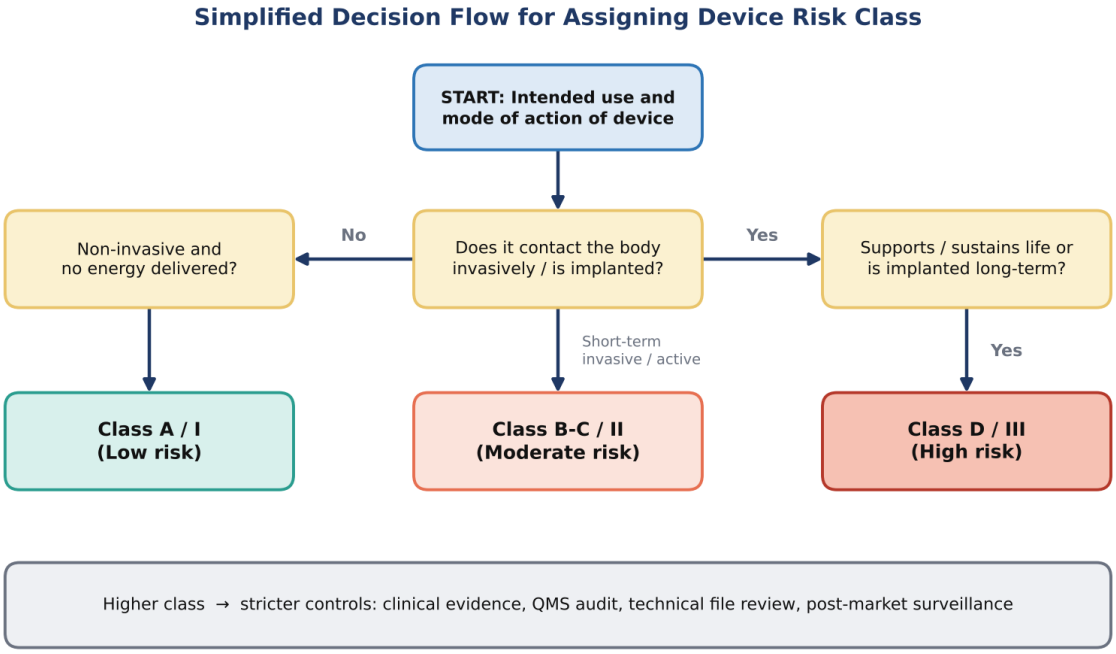

Fig. 1.4 Simplified decision flow for assigning device risk class

➢ Risk-based classification systems

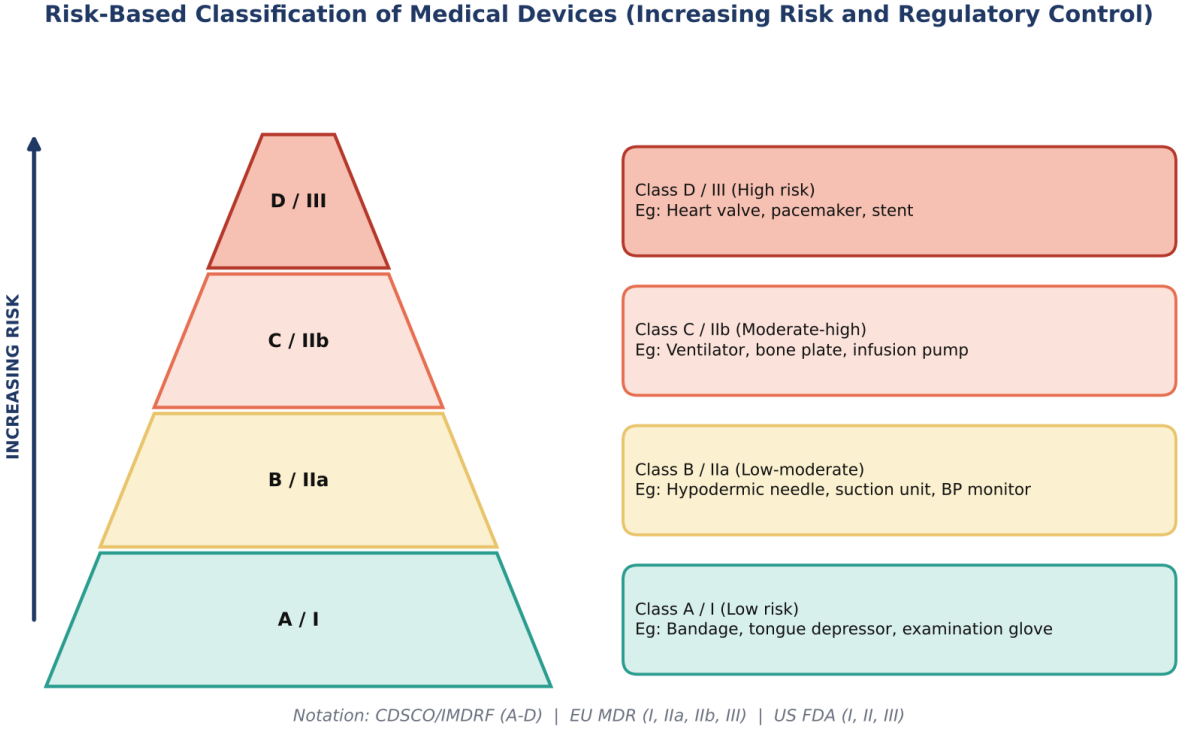

Fig. 1.5 Risk-based classification of medical devices with examples

A. United States (FDA)

The US Food and Drug Administration classifies devices into **Class I, II and III** under the Federal Food, Drug and Cosmetic Act. Each class implies a set of regulatory controls.

Table 1.7 US FDA device classes

Class	Risk level and controls	Premarket route	Examples
Class I	Low risk; general controls only (registration, listing, labelling, good manufacturing practice)	Most are exempt from premarket notification	Elastic bandage, examination gloves, hand-held surgical instruments, tongue depressor
Class II	Moderate risk; general controls plus special controls (performance standards, post-market surveillance, guidance)	510(k) premarket notification showing substantial equivalence to a predicate; De Novo for novel low-to-moderate risk devices	Powered wheelchair, infusion pump, ECG machine, pregnancy test kit, blood pressure cuff
Class III	High risk; supports or sustains life, is implanted or presents potential unreasonable risk of illness or injury	PMA (premarket approval) with clinical data from valid scientific evidence	Implantable pacemaker, heart valve, implantable defibrillator, breast implant

Since **2 February 2026** the FDA's Quality Management System Regulation (QMSR) has applied; it replaces the older Quality System Regulation in 21 CFR Part 820 by incorporating **ISO 13485:2016** by reference. Design and development requirements apply to Class II, Class III and certain Class I devices.

B. European Union (EU MDR 2017/745)

The EU Medical Device Regulation uses **Class I, IIa, IIb and III** based on 22 classification rules (Annex VIII), considering duration of contact, invasiveness and whether the device is active. Class I (non-sterile, non-measuring) can be self-certified, while higher classes need a **notified body** audit and technical documentation review before the **CE mark** is affixed.

C. IMDRF / GHTF model (A to D)

Table 1.8 IMDRF / GHTF risk classes

Class	Risk to individual / public health	Typical examples	Conformity expectation
A	Low individual risk, low public health risk	Surgical retractors, tongue depressors, wheelchairs	Registration; quality system basics
B	Low-moderate individual risk and/or low public health risk	Hypodermic needles, suction equipment, BP monitors	Quality system; limited technical review
C	Moderate-high individual risk and/or moderate public health risk	Lung ventilators, bone fixation plates, X-ray machines	Full quality system audit, technical file review, clinical evidence
D	High individual risk and/or high public health risk	Heart valves, implantable defibrillators, stents	Strictest review, clinical investigation, audit by authority

D. India (Medical Devices Rules, 2017 - CDSCO)

India follows the four-class risk-based model (A, B, C, D) under the Medical Devices Rules, 2017, framed under the Drugs and Cosmetics Act, 1940. The manufacturing licence for **Class A and B** is granted by the **State Licensing Authority** (application in Form MD-3, licence in Form MD-5), while **Class C and D** are licensed by the **Central Licensing Authority** (CDSCO), with application in Form MD-7 and licence in Form MD-9. Import of any class needs a CDSCO import licence. Licensing of previously unregulated ("non-notified") devices was phased in: Class A and B from **1 October 2022** and Class C and D from **1 October 2023**.

Table 1.9 India: classes, examples and licensing authority

Class	Risk	Examples (CDSCO)	Manufacturing licence
A	Low	Alcohol swabs, tongue depressors, absorbent cotton and gauze	State Licensing Authority (Form MD-3 / MD-5)
B	Low-moderate	Hypodermic needles, suction equipment, digital thermometers, BP monitors	State Licensing Authority (Form MD-3 / MD-5)
C	Moderate-high	Ventilators, bone fixation plates, X-ray machines, dialysis machines, glucometers (IVD)	Central Licensing Authority (Form MD-7 / MD-9)
D	High	Heart valves, stents, implantable defibrillators	Central Licensing Authority (Form MD-7 / MD-9)

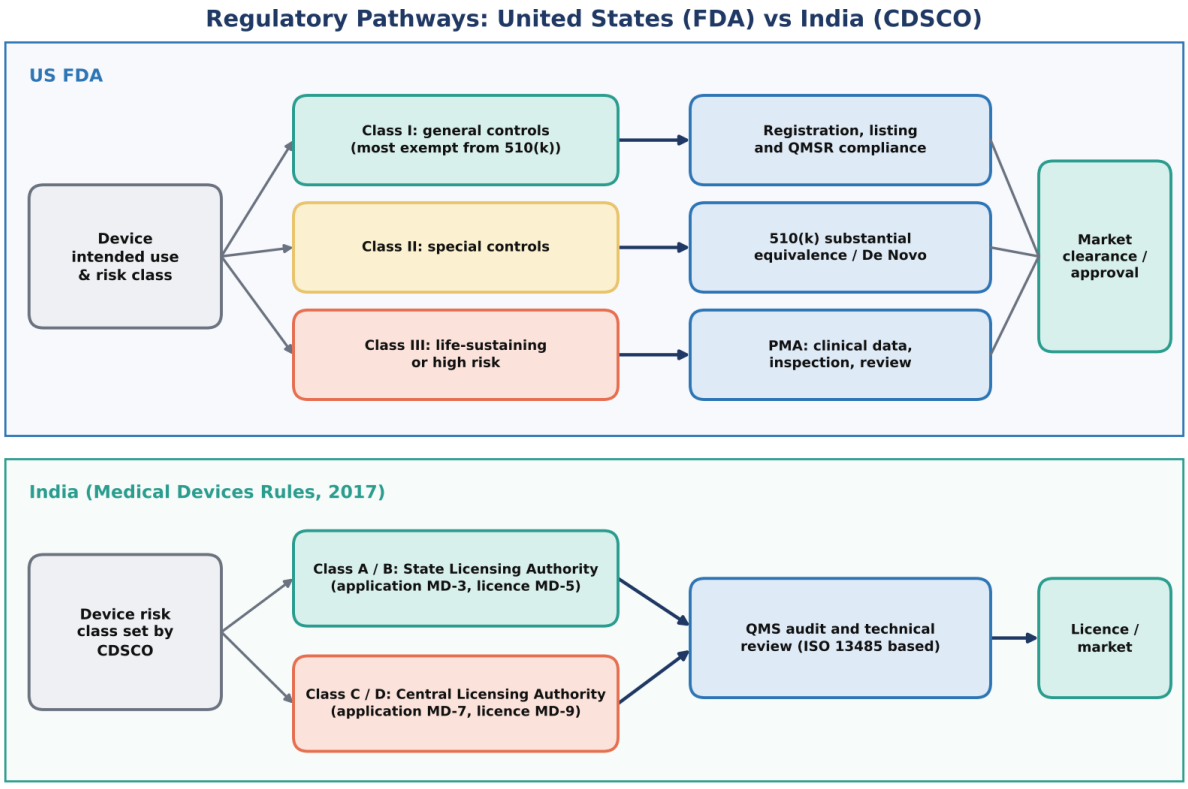

Fig. 1.6 Regulatory pathways: United States (FDA) and India (CDSCO)

Table 1.10 Comparison of classification systems

Risk level	India (CDSCO)	IMDRF / GHTF	EU MDR	US FDA
Lowest	Class A	Class A	Class I	Class I
Low-moderate	Class B	Class B	Class IIa	Class II
Moderate-high	Class C	Class C	Class IIb	Class II / III
Highest	Class D	Class D	Class III	Class III

Design implication
Higher the class, higher the burden of proof: more design verification, clinical evidence, quality system audit, and post-market surveillance. Early classification decides project cost and timeline. A device with a sterile or measuring function may be placed in a higher class than a similar non-sterile one.

➢ **Classification by other criteria**

- **By energy use:** active (powered) devices such as pumps and monitors versus passive devices such as bandages and implants.
- **By invasiveness:** non-invasive (external), invasive through a body orifice, surgically invasive, implantable.
- **By duration of use:** transient (<60 min), short term (up to 30 days), long term (>30 days).
- **By place of use:** hospital, clinic, ambulance, home, community or field setting.
- **By electrical safety (IEC 60601-1):** Class I (protective earth), Class II (double insulation) and internally powered; applied parts Type B, BF and CF.

➢ **Risk: basic terminology**

Table 1.11 Risk management terms (ISO 14971)

Term	Meaning	Example
Hazard	Potential source of harm	Electrical energy, sharp edge, toxic material, wrong drug dose
Hazardous situation	Circumstance in which people are exposed to a hazard	Leaking current reaches a patient during a procedure
Harm	Physical injury or damage to health	Burn, electric shock, infection, death
Severity	Measure of the possible consequences of a hazard	Negligible, minor, serious, critical, catastrophic
Probability	Likelihood of harm occurring	Improbable, remote, occasional, probable, frequent
Risk	Combination of the probability of occurrence of harm and its severity	Risk = Severity x Probability
Residual risk	Risk remaining after risk controls are applied	Small chance of alarm failure after redundancy added

Term	Meaning	Example
Benefit-risk	Comparison of medical benefit to the remaining risk	Pacemaker: some surgical risk vs life-saving benefit

➢ **Risk management process (ISO 14971)**

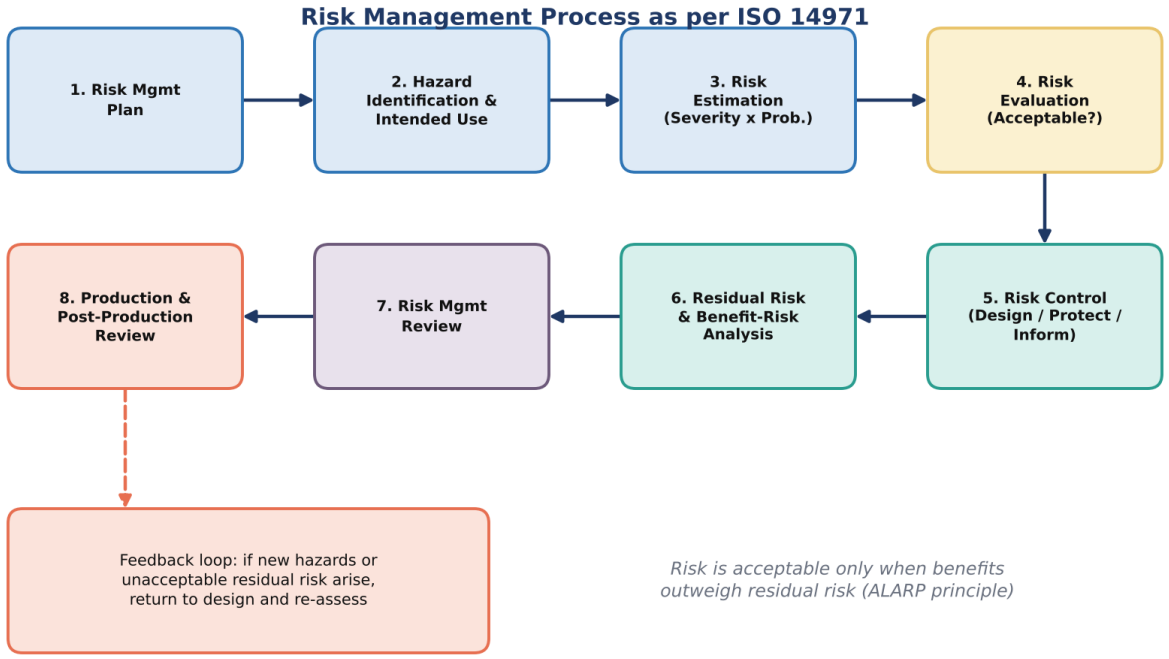

Fig. 1.7 Risk management process as per ISO 14971

1. **Plan:** define scope, responsibilities, risk acceptability criteria and review points in a Risk Management Plan.
2. **Identify hazards:** based on intended use, reasonably foreseeable misuse, user profiles, and device characteristics (use techniques such as FMEA, FTA, HAZOP, PHA).
3. **Estimate risk:** assign severity and probability for each hazardous situation.
4. **Evaluate risk:** compare with the acceptability criteria (risk matrix).
5. **Control risk:** apply measures in priority order (see below), then re-evaluate.
6. **Evaluate residual and overall risk:** confirm that benefits outweigh the remaining risk.
7. **Review and report:** compile the Risk Management File before release.
8. **Production and post-production:** monitor complaints, incidents and field data; update the risk file.

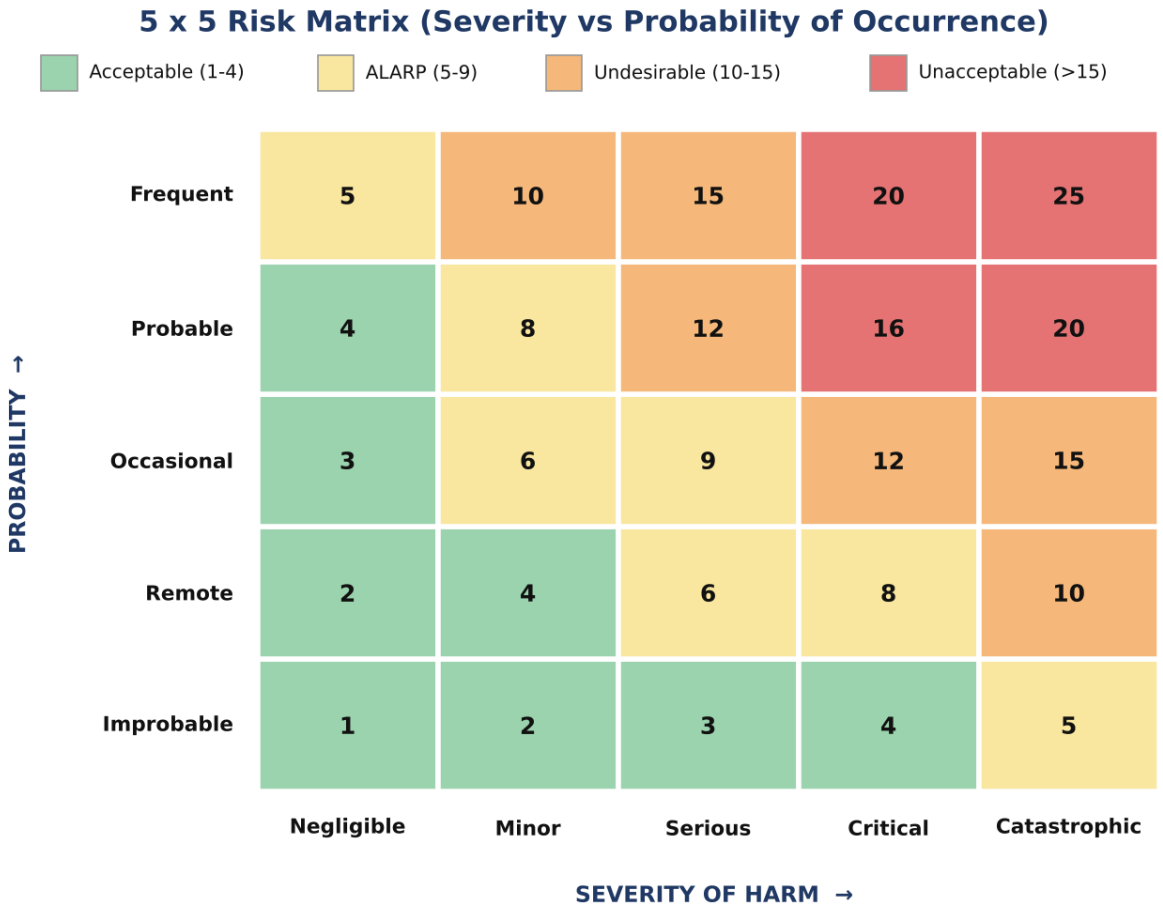

Fig. 1.8 5 x 5 risk matrix (severity versus probability)

Hierarchy of risk control measures

Table 1.12 Order of priority for risk controls

Priority	Control type	Description	Example (infusion pump)
1	Inherently safe design	Remove the hazard or reduce it by design	Pump limited to a maximum safe flow rate by hardware
2	Protective measures	Add safeguards and alarms in the device or manufacturing process	Air-in-line detector, occlusion alarm, drug library with dose limits
3	Information for safety	Labels, instructions, training, warnings	Warning label, training manual, on-screen prompts

Remember
Always apply controls in this order. Warnings and training are the weakest control and cannot replace safe design.

Worked example: simplified risk analysis (FMEA style) of a portable ECG monitor

Table 1.13 Sample hazard analysis

Hazard	Cause	Severity	Prob.	Control	Residual risk
Electric shock	Leakage current from faulty isolation	5	1	Double insulation, CF-type applied part, leakage test	Acceptable
Wrong diagnosis	Noise creates false ST changes	4	3	Digital filters, lead-off detection, signal-quality index	ALARP
No alarm for arrhythmia	Software algorithm failure	5	2	Watchdog, redundancy, software verification (IEC 62304)	ALARP
Skin irritation	Electrode adhesive reaction	2	3	Biocompatibility testing (ISO 10993), label warning	Acceptable
Device stops in use	Battery depletion	3	3	Low-battery warning, battery fuel gauge	Acceptable

➢ Key standards linked to classification and risk

Table 1.14 Important standards for medical devices

Standard	Title / Scope	Used for
ISO 13485	Quality management systems for medical devices	Company-level QMS; basis for regulations in India, EU, US (QMSR)
ISO 14971	Application of risk management to medical devices	Hazard analysis and risk control
IEC 60601-1	Basic safety and essential performance of medical electrical equipment	Electrical, mechanical, thermal and fire safety
IEC 60601-1-2	Electromagnetic disturbances: requirements and tests	EMC immunity and emissions
IEC 62304	Medical device software lifecycle processes	Software development and maintenance
IEC 62366-1	Application of usability engineering to medical devices	Human factors and use-safety
ISO 10993 series	Biological evaluation of medical devices	Biocompatibility testing
ISO 11135 / 11137 / 17665	Sterilization by ethylene oxide / radiation / moist heat	Sterilization validation

Remember

Exam tip: For "classification and risk" questions, give: need for classification, factors, comparison table of India/EU/US classes with examples, the risk management process figure, risk matrix, and the control hierarchy.