Principles of Medical Devices Classification

GHTF/SG1/N15:2006

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European Commission

Principles of Medical Devices Classification

Why Classify?

Answer:

- **Economic and effective control of devices**
- **Resources in line with Risk**

- Why Classify?
- Rationale Used
- Risk Class and Technical Documentation
- Recommendations
- Factors
- The Rules
- Who Classifies?
- Common Errors
- Changes to Classification

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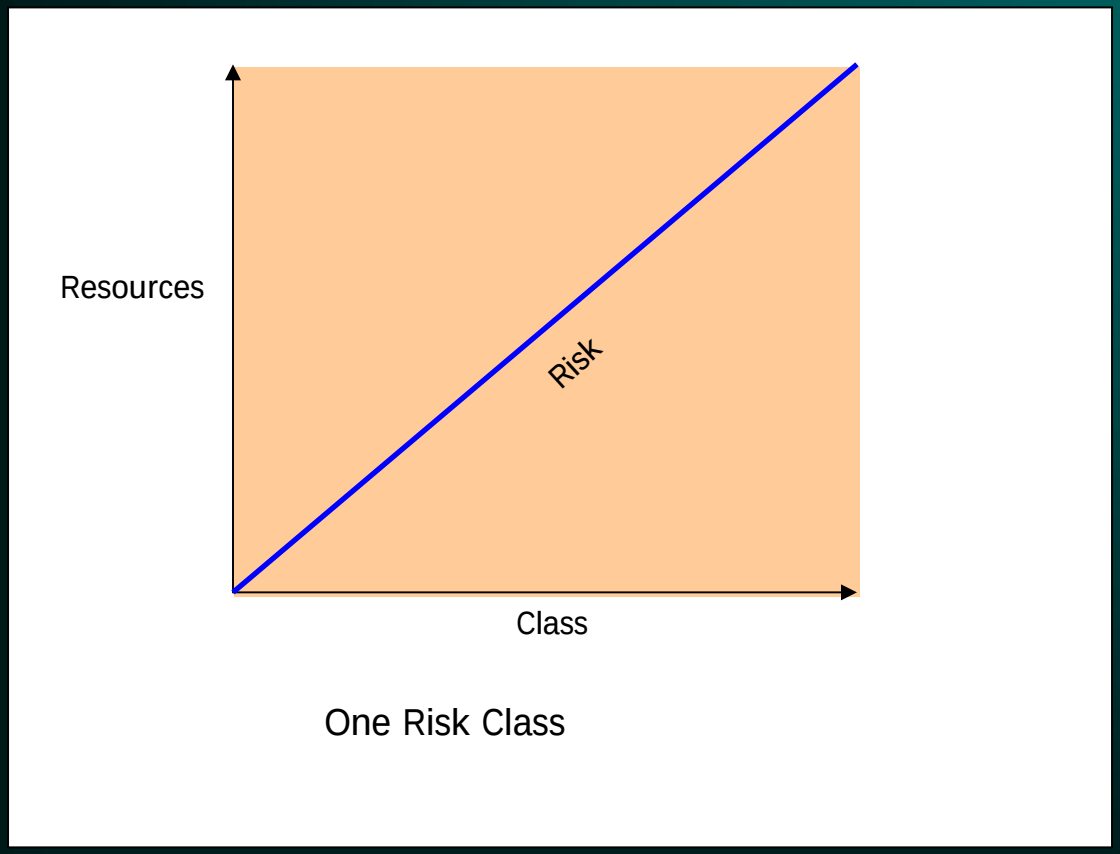

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Two Risk Classes

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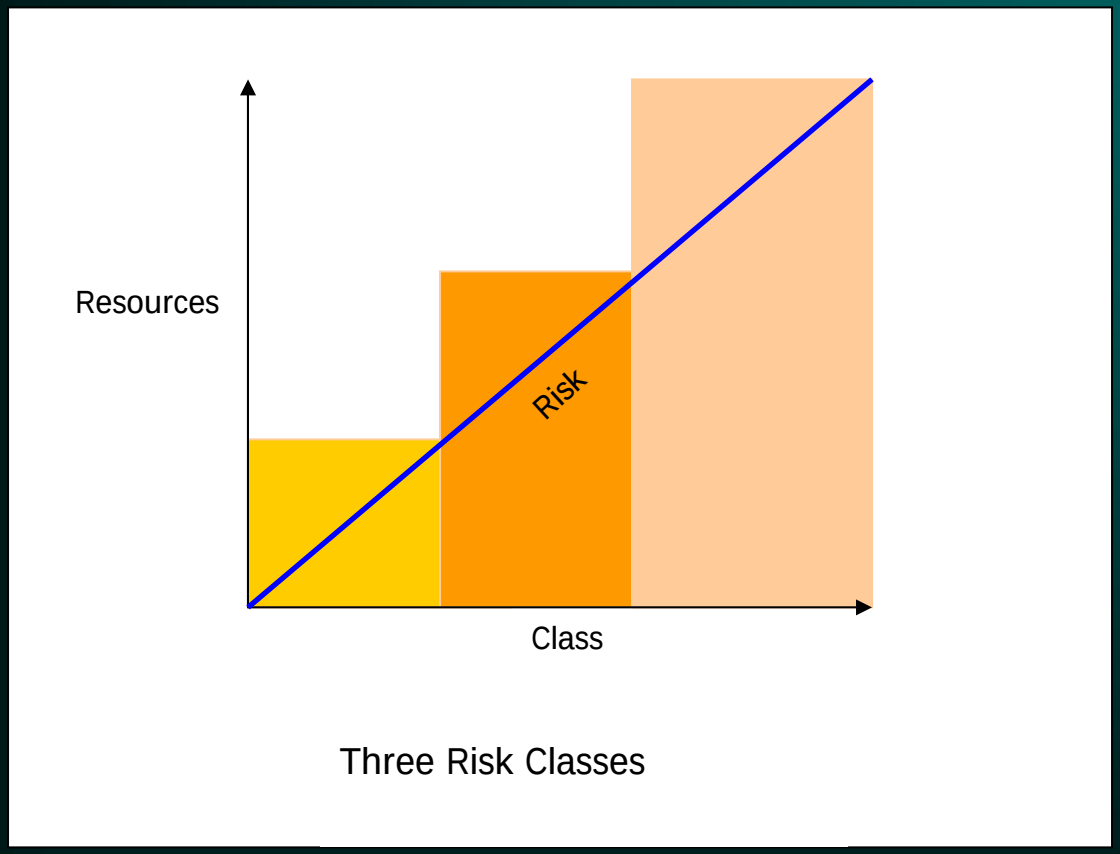

Three Risk Classes

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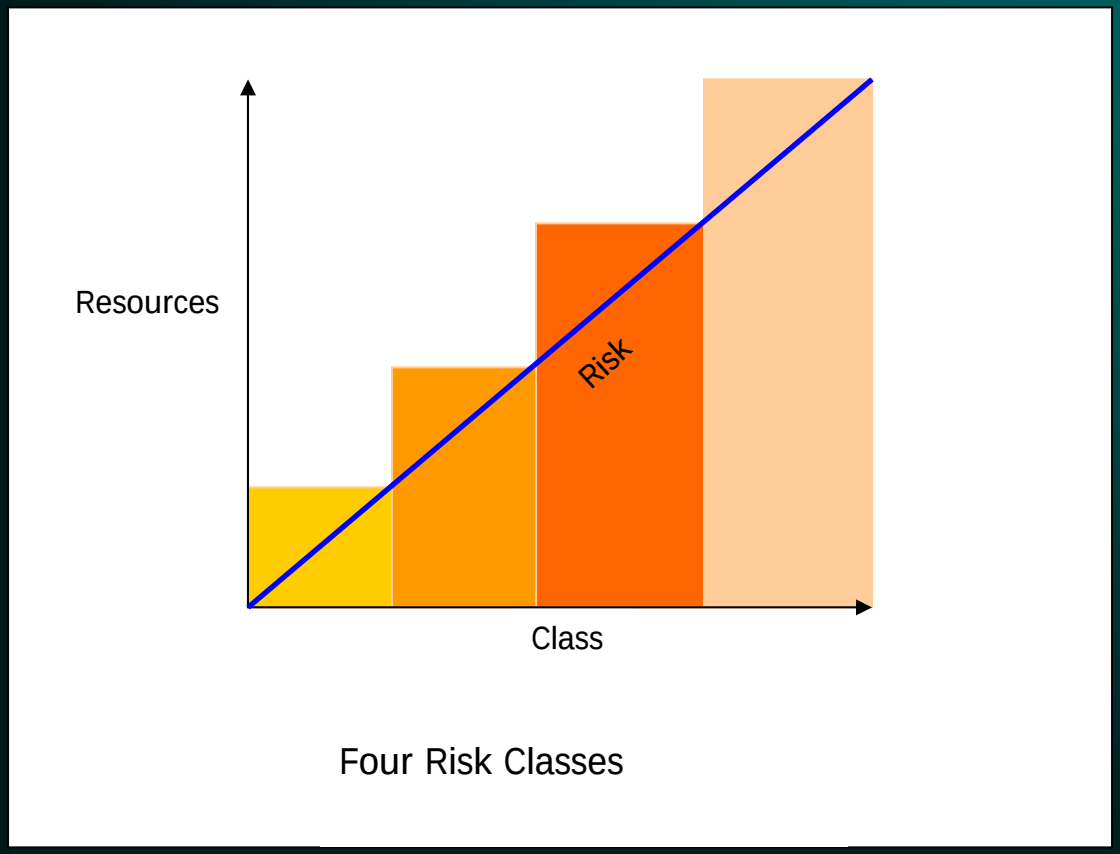

Four Risk Classes

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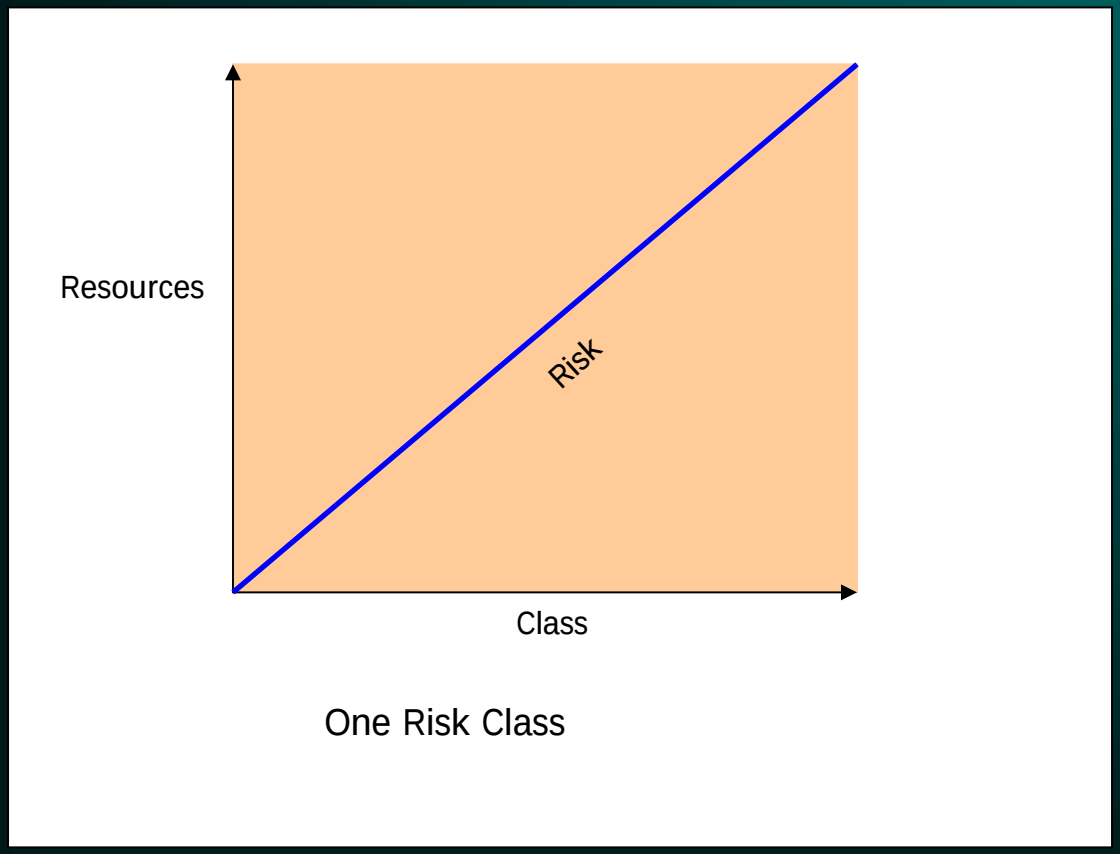

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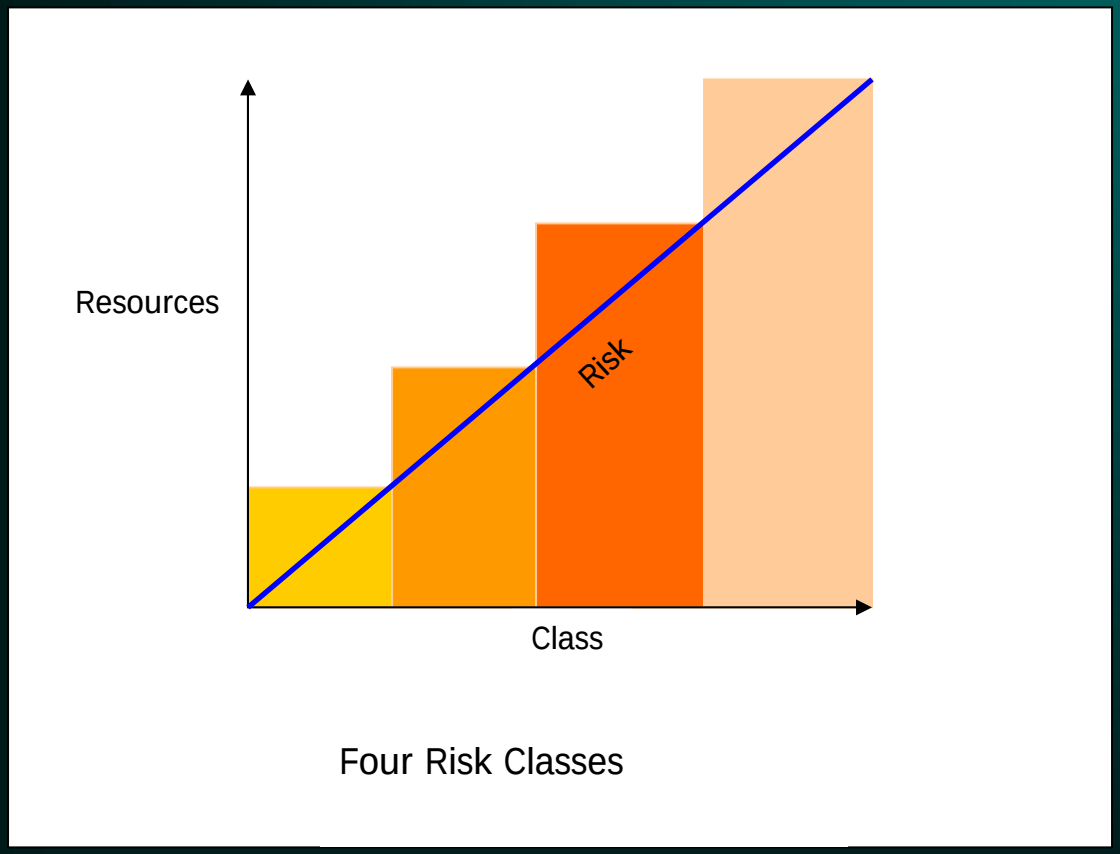

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Why Classify?

Why four classes?

Answer:

Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls.

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Rationale Used

What makes a product fall in a certain class and not another?

Answer:

Risk to patients, users and other persons

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Principles of Medical Devices Classification

Risk to patients, users and other persons

Which in turn depends on:

- Intended purpose
- Risk management applied
- Intended Users
- Mode of Operation or Technologies

- (Also Novel Devices)

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Risk Class and Technical Documentation

Common Misconception:

The lower the risk class the less technical documentation is needed

Reality:

All the Essential Principles apply no matter the risk class; it is the characteristics of the device that determine the depth and detail of the technical documentation

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Including Clinical Evidence!!!!

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Recommendations

Primary Recommendations (The logic of the system)

- Strive to be global
- 4 classes
- Rules should lead to consistency between manufacturers and regulators
- Clear
- Robust to technology
- Manufacturers should document their determination of the risk classification and under which rule or rules
- Final determinations that deviate should be balanced against disharmonization

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Factors

- Duration and nature of contact
- Delivering a Medicinal Product or Energy
- Biological Effects
- Multiple Rules Applying – highest risk class applies
- Discrete Classification – separate application of rules
- Combinations – Change in intended use; Not yet approved devices
- Accessories
- Software
- Subject to Change

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The Rules

Currently 16 rules in 4 Sections

- Non-invasive Devices
- Invasive Devices
- Active Devices
- Additional Rules

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The Rules

Additional Rules

- Medicinal Products
- Animal or Human Tissues
- Disinfectants
- Contraceptives

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Who Classifies?

Initially classification by the Manufacturer (Documented)

followed by

Final, confirmatory, classification by the Regulatory Authority

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Common Errors

- Not a device
- Stop at first rule that fits
- Ignore sub-paragraphs to the rules (unless...)
- Not realize that one of the 'Additional Rules' applies
- Misinterpret definitions, e.g. degrees of invasiveness

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Changes to Classification

Jurisdictions may have to adjust their classification

- Post-market Experience
- Historical Knowledge
- National Rules

And GHTF itself will review this document

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Thank You For Listening

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