Preserving Innovation

Strategic Sample Management for MedTech Growth and Compliance

5th of June 2025

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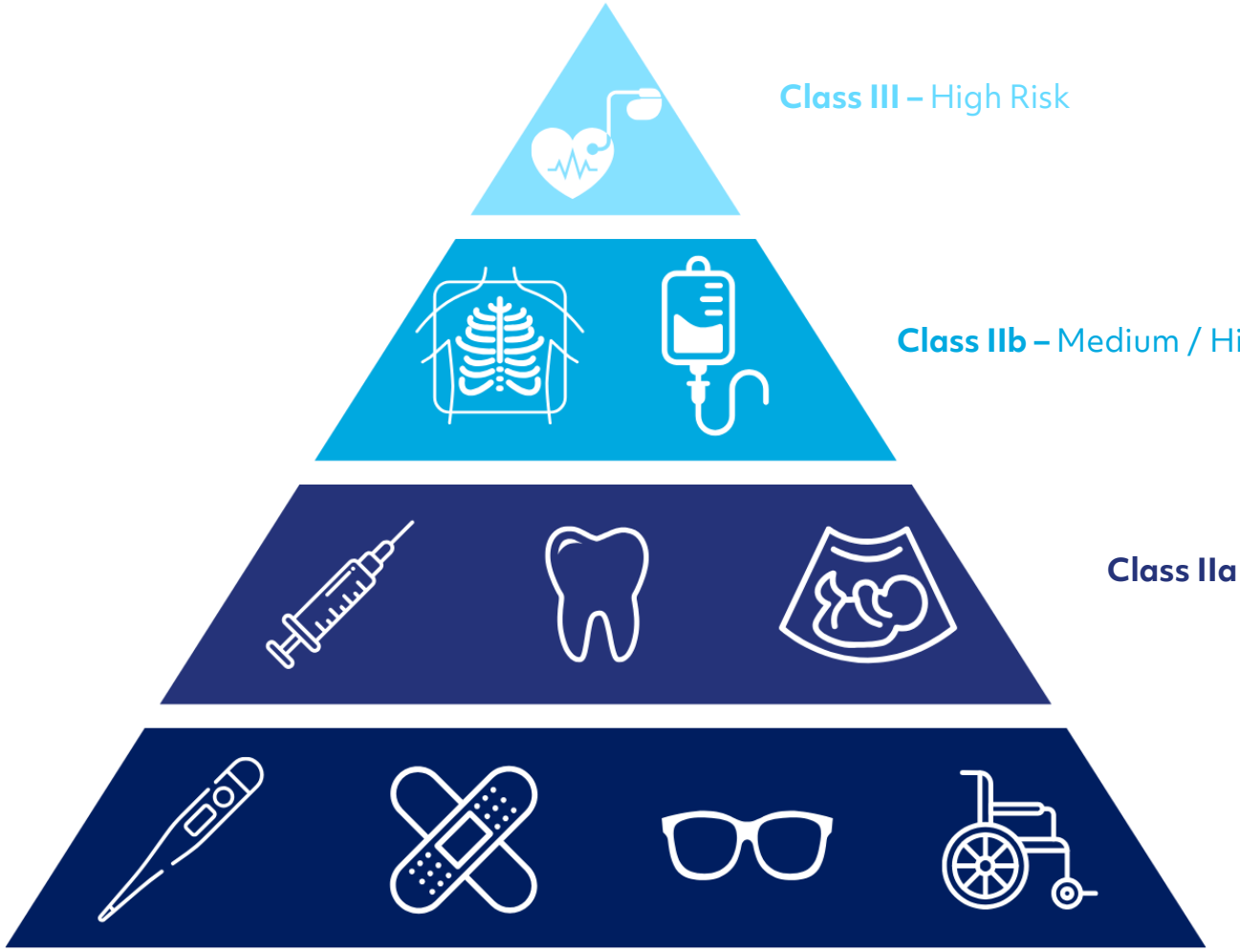
Regulation 7 of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

Medical Devices Come in Many Shapes, Sizes and Types…

Types of Medical Devices - 6 Classes

High Risk



Low Rist

Class III – High Risk

Class IIb – Medium / High Risk

Class IIa – Low / Medium Risk

Class I – Low Risk
- Class Is : Sterile
- Class Im: Measure
- Class Ir : Reusable

Class I (s, m & r)

- Pose minimal potential for harm to the user
- Examples:
  - Sterile: Bandages, syringes without needles
  - Measure: Thermometers
  - Reusable: Elastic bandages, stethoscopes and orthopaedic shoes
- Lowest level of regulatory controls
- Have a low risk profile

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Class IIa

- Short-term use
- Corrective contact lenses, standard hearing aids, TENS devices, dental fillings, surgical clamps
- Certified by a notified body
- Have a medium risk profile

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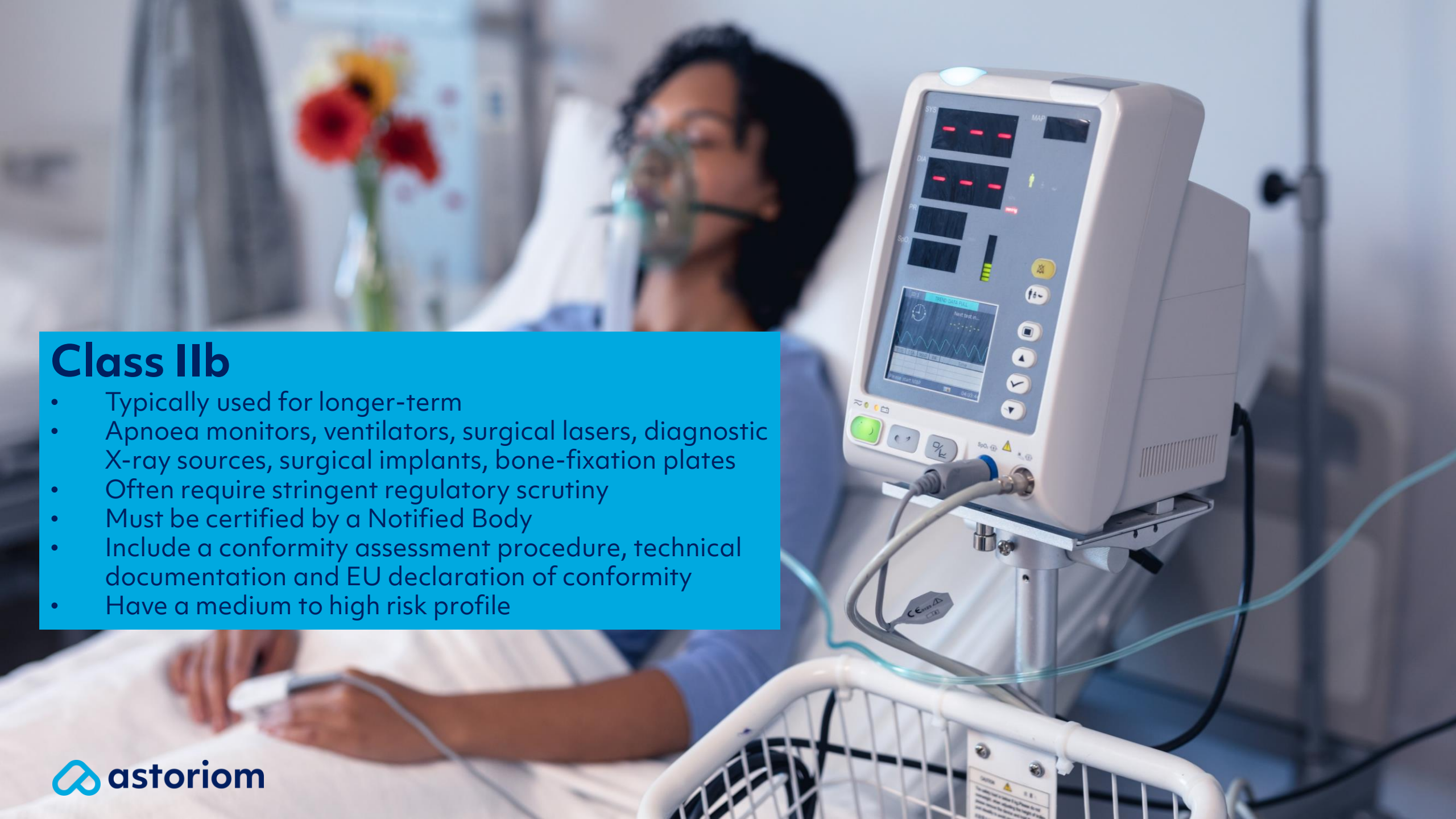

Class IIb

- Typically used for longer-term
- Apnoea monitors, ventilators, surgical lasers, diagnostic X-ray sources, surgical implants, bone-fixation plates
- Often require stringent regulatory scrutiny
- Must be certified by a Notified Body
- Include a conformity assessment procedure, technical documentation and EU declaration of conformity
- Have a medium to high risk profile

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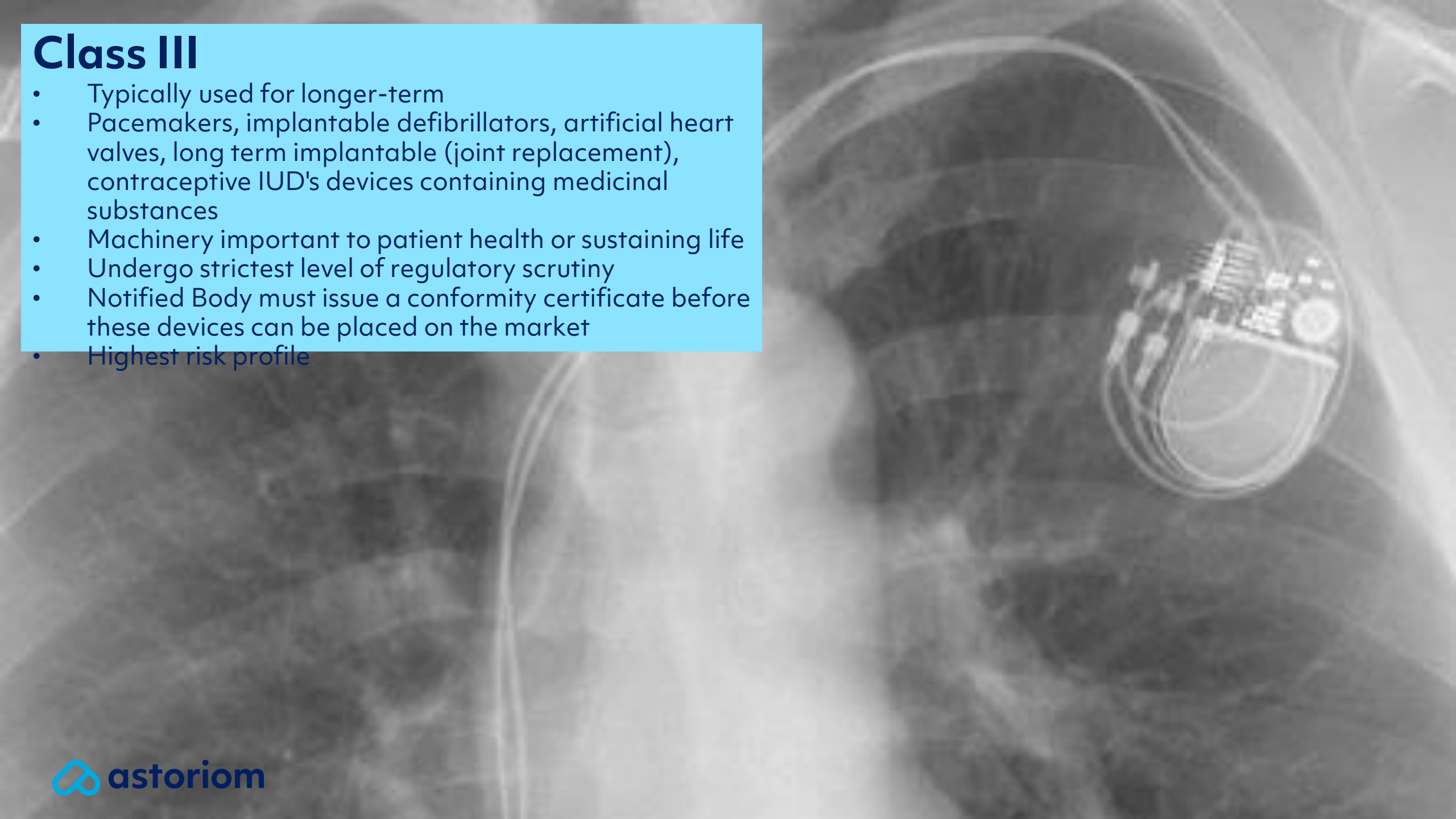
Class III

- Typically used for longer-term
- Pacemakers, implantable defibrillators, artificial heart valves, long term implantable (joint replacement), contraceptive IUD's devices containing medicinal substances
- Machinery important to patient health or sustaining life
- Undergo strictest level of regulatory scrutiny
- Notified Body must issue a conformity certificate before these devices can be placed on the market
- Highest risk profile



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Class Im

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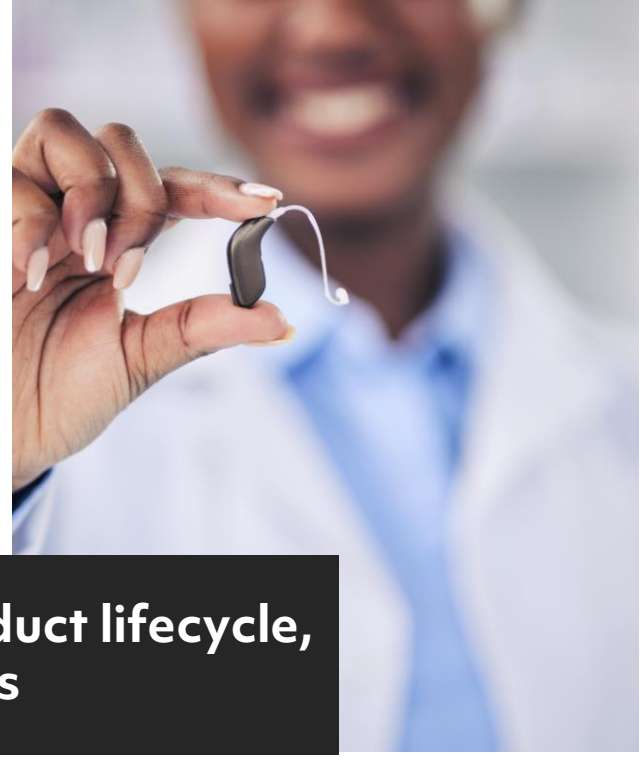


Across the patient and product lifecycle, medical devices

-whether implantable, wearable, or diagnostic—

require robust storage and traceability protocols



Challenges & Risks

of R&D Sample Sustainability in the Medical Device Sector

- **Regulations:** complex and varying global regulatory requirements
- **Diverse sample types:** polymers, tissues, diagnostic reagents, and sensor materials all require tailored storage and monitoring strategies
- **Skilled personnel and certified storage facilities:** critical for ensuring proper documentation, chain of custody, and storage compliance
- **Sample handling and storage requirements:** depending on device classification and function
- **Packaging & transport:** improper conditions during sample transport can jeopardise the viability of materials
- **Stability data supporting regulatory submissions:** critical for product approval and distribution
- **Unforeseen disasters:** can destroy samples & delay research

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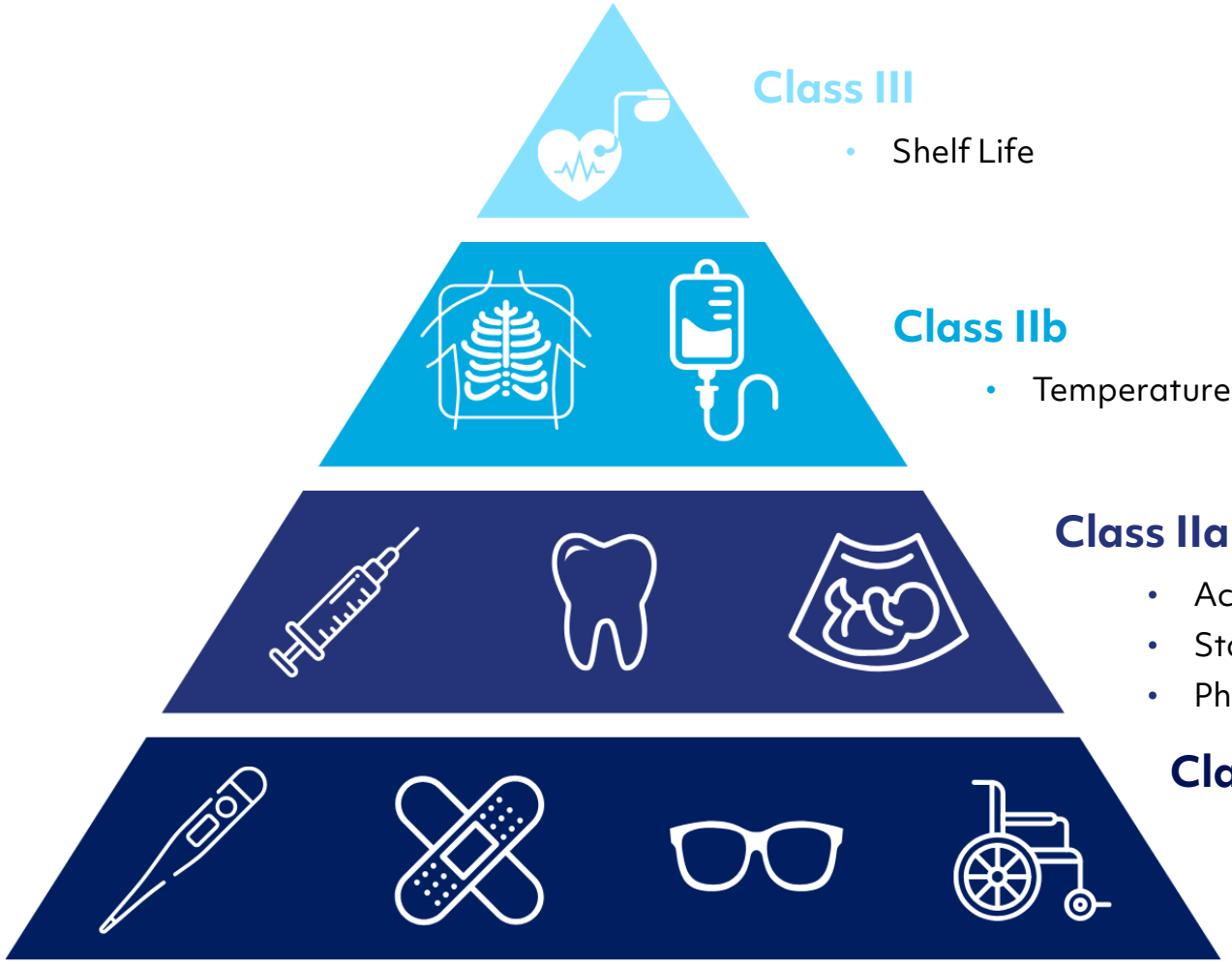
Supporting Medical Devices

High Risk



Low Rist

Class III

- Shelf Life

Class IIb

- Temperature Cycling

Class IIa

- Accelerated Ageing
- Stability Storage
- Photostability

Class I

- **Class Is**: Material Shelf Life – Temperature Cycling
- **Class Im**: Stability Storage and Stability Testing
- **Class Ir**: Shelf Life - Temperature Cycling

Our Success Stories
Orthopaedic Franchise

Stability Storage

Bone Cement

Changes in Medical Device Directive

Not Enough Capacity

Astoriom's Offer:

Business Continuity

Regulatory Knowledge

Capacity

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Our Success Stories
Leading Supplier of tubes and catheters

Accelerated Ageing

Medical Tubes and Catheters

Changes in Medical Device Directive

No Capacity for Specific Temperature

Astoriom's Offer:

Business Continuity

Quick Response

Supply Data for Medical Submission - MHRA

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Safeguarding Samples
Every Step of the Way

Visit us at **booth G58**

Thank you!

Wendy Cullen

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