

# **Navigating EU MDR and Regulatory Challenges for Medical Device Success**

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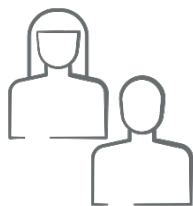
# Smith+Nephew at-a-glance

## What we do...

- A portfolio medical technology business
- Focused on the repair, regeneration and replacement of soft and hard tissue.
- We exist to restore people's bodies and their self-belief by using technology to take the limits off living.
- We call this purpose... **Life Unlimited!**

## 3 global business units:

- Orthopaedics
- Sports Medicine & ENT
- Advanced Wound Management



**17,000**

Employees serving  
~100 markets



**14+ million**

patients treated with  
our products p.a.



**\$289 million**

R&D investment in 2024



**FTSE100**

A constituent of the  
UK's FTSE100, our  
shares are traded in  
London and New York



**16**

New product  
launches in 2024



**\$5.8B Revenue in 2024**

# Global Footprint



**1856**  
Smith+Nephew starts off with presence in the UK

## Operating in more than 100 Countries

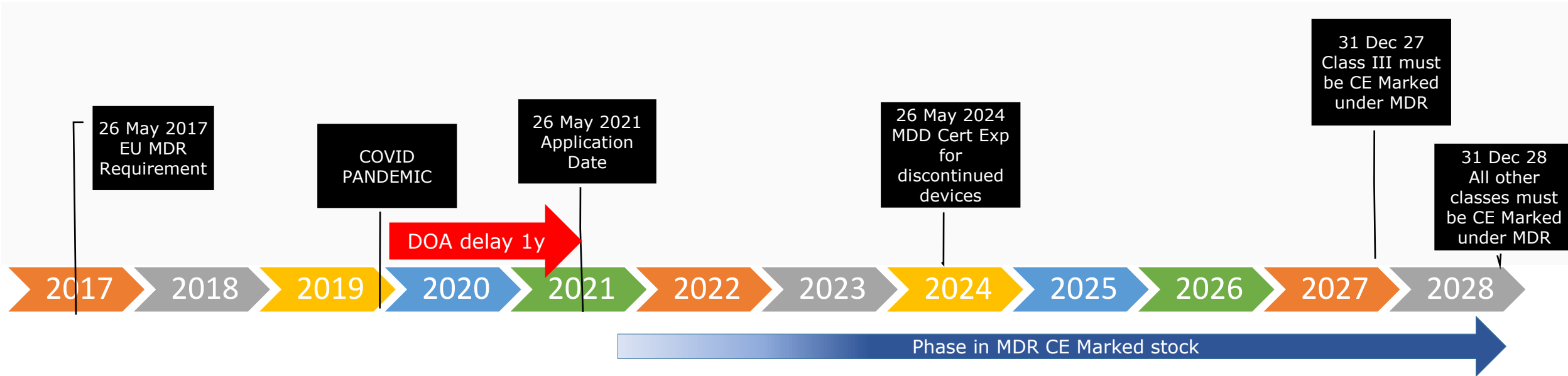


# Topics Covered

- + **EU MDR Overview**
- + **Critical MDR Impacts on Product Development and Quality Systems**
- + **Optimizing Recertification Strategies to Minimize Disruption and Ensure Continuity**
- + **Strengthening Post-Market Surveillance to Meet Rigorous MDR Expectations**
- + **Evaluating MDR's Market Access Implications Across Product Lifecycles**
- + **Turning Compliance Into a Strategic Advantage Through Proactive MDR Alignment**



# EU MDR Timeline



- **26 May 2021** – Class I devices must be CE Marked under MDR to be placed on the EU Market
- **26 May 2024** - All MDD Certificates expire for devices that are not being CE Marked under MDR
- **31 Dec 2027** – MDD Certificates expire for Class III devices being CE Marked under MDR. Only MDR CE Marked Class III devices can be placed on the EU market after this date.
- **31 Dec 2028** - MDD Certificates expire for all other classes of devices being CE Marker under MDR. Only MDR CE Marked Class IIB, IIA, IS, IR, IM devices can place on the EU market after this date.

# Critical MDR Impacts on Product Development & Quality Systems



# EU MDR is a Significant European Law Change

A paradigm shift in the way CE-marked medical devices are placed on the market



20 articles  
60 pages  
12 annexes

Under the MDD the **manufacturer could certify** meeting technical requirements and place on the market

97 articles  
369 pages  
16 annexes

Under the MDR manufactures **MUST** provide evidence on clinical benefits to patients

MDR rules to be fulfilled to **CE mark a medical device** and make it available on **CE-recognizing markets**

Stands alone, **not following FDA or other bodies**

## Stricter Clinical Evaluation Requirements

- Greater emphasis on clinical data and clinical evaluation reports (CERs).
- Clinical evidence to support claims for Legacy devices .
- Increased need for post-market clinical follow-up (PMCF) and real-world data.

## Rigorous Risk Management

- Risk management & requirements throughout product life-cycle.
- Risks reduction as far as possible, not just to an acceptable level.

## UDI (Unique Device Identification) Requirements

- UDI for traceability for each devices.
- Impacts labeling, packaging, and traceability systems from design through distribution.

## Expanded Technical Documentation

- Detailed technical files requirements
  - Benefit-risk analysis
  - Justification for equivalence (if claimed)
  - Complete design history
- Documentation update availability to Notified Bodies.

## Stringent Classification Rules

- Possible reclassification of devices to higher risk categories (e.g., some software or implants).
- Influences on development timelines and regulatory pathways.

## Stronger Emphasis on Usability Engineering

- Human factors and usability must be integrated into design from the start.
- Requires compliance with standards like IEC 62366.

## Lifecycle and Post-Market Surveillance Integration

- Design must support post-market surveillance (PMS) and vigilance activities.
- Requires integration of feedback mechanisms into product design.

## Alignment with ISO 13485:2016

- MDR mandates QMS compliance aligning with ISO 13485:2016.
- Broader scope (i.e. supplier controls, risk management, and software validation).

## Enhanced Documentation and Record-Keeping

- Requirements for **permanent accessibility** of certain documentation (e.g., Declaration of Conformity).
- Emphasis on **traceability**, audit trails, and structured document control.

## Mandatory Person Responsible for Regulatory Compliance (PRRC)

- Organizations must designate a **PRRC** with defined responsibilities.
- Adds accountability and formalizes regulatory oversight in QMS.

## Stricter Supplier and Subcontractor Controls

- Must ensure **contractual clarity** and oversight of outsourced processes.
- Expanded requirements for supplier qualification and performance monitoring.

## Vigilance and Post-Market Surveillance (PMS) System Integration

- PMS must be **proactive and systematic**, not just reactive.
- Devices need a **PMS plan, Periodic Safety Update Reports (PSURs)** for Class IIa and above.

## Increased Scrutiny by Notified Bodies

- Audits are more frequent, detailed, and include **unannounced inspections**.
- QMS must be audit-ready at all times with clear, structured evidence trails.

## Change Control and Re-certification Burdens

- Even minor changes may trigger reassessment under MDR.
- Companies must implement robust **design and change control** systems

# Optimizing Recertification Strategies to Minimize Disruption and Ensure Continuity



# Understanding Recertification Requirements



## Valid Certificate Transition

- MDD certificates issued before 26 May 2021 can remain valid until:
  - 31 December 2027 (Class IIb implantable and Class III)
  - 31 December 2028 (Class IIa and I devices under NB involvement)

## Reclassification Considerations

- MDR includes stricter classification rules (i.e. some devices previously Class I or IIa under MDD may now fall into higher classes).

## Clinical Evaluation Requirements

- Robust clinical evidence
- Legacy devices without sufficient clinical data will need new data generation or clinical trials.

## Risk Management

- Must be lifecycle-based.
- Updated per ISO 14971:2019.

## QMS Compliance with MDR

- QMS must be certified or aligned with ISO 13485:2016 and MDR requirements.
- Tech Documentation must meet Annex II and III .

## UDI System Implementation

- All devices must comply with Unique Device Identification (UDI) rules.
- Technical documentation must reference the UDI-DI.

## Post Market Surveillance/Vigilance

- PMS Plan, PSUR, PMCF as applicable.
- Regular surveillance audits by Notified Bodies.
- Increased scrutiny Class III/implantable devices .

# Optimizing Recertification Strategies to Minimize Disruption and Ensure Continuity

## Portfolio Prioritization & Risk Assessment

- Conduct a full portfolio review.
- Rank by market impact, regulatory complexity, and certification risk.
- Consider rationalizing low-margin or low-volume SKUs.

## Timeline Management & Proactive Planning

- Map certificate expiration dates and key milestones.
- Apply the "Start Early" principle: Begin MDR recertification planning 24–30 months before expiry.
- Establish clear internal deadlines ahead of NB timelines.

## Documentation Readiness & Gap Closure

- Perform a gap analysis of all documentation against MDR Annex II & III.
- Update technical files, CERs, and risk documentation early.
- Prepare device-specific documentation modules for faster scalability.

## Early & Continuous Notified Body (NB) Engagement

- Secure a Notified Body slot early — demand is high and capacity is limited.
- Share preliminary documentation to get feedback before formal submission.
- Maintain an open line with NB for changes, interpretations, and reviews.

## Continuity & Contingency Planning

- Implement buffer stock and explore parallel market registration for continuity.
- Develop an emergency plan.

# Strengthening Post-Market Surveillance to Meet Rigorous MDR Expectations



# Strengthening Post-Market Surveillance to Meet Rigorous MDR Expectations



## PMS System

- Implement robust data collection and monitoring mechanisms.

## PMCF Planning

- Design PMCF studies to fill clinical gaps and assess long-term safety.

## Vigilance & Reporting

- Establish a vigilance system for reporting adverse events to EUDAMED.

## PSUR & Clinical Evidence

- Regularly update PSURs and clinical evaluations with post-market data.

## Continuous Monitoring

- Utilize data analytics to detect trends and adjust PMS strategies.

## Transparency & Compliance

- Maintain auditable records and ensure timely reporting to regulators.

# Evaluating MDR's Market Access Implications Across Product Lifecycles



# Market Entry and Registration Hurdles

## Complex Registration Processes

- Market entry involves navigating complex registration processes that can be time-consuming and challenging for manufacturers.

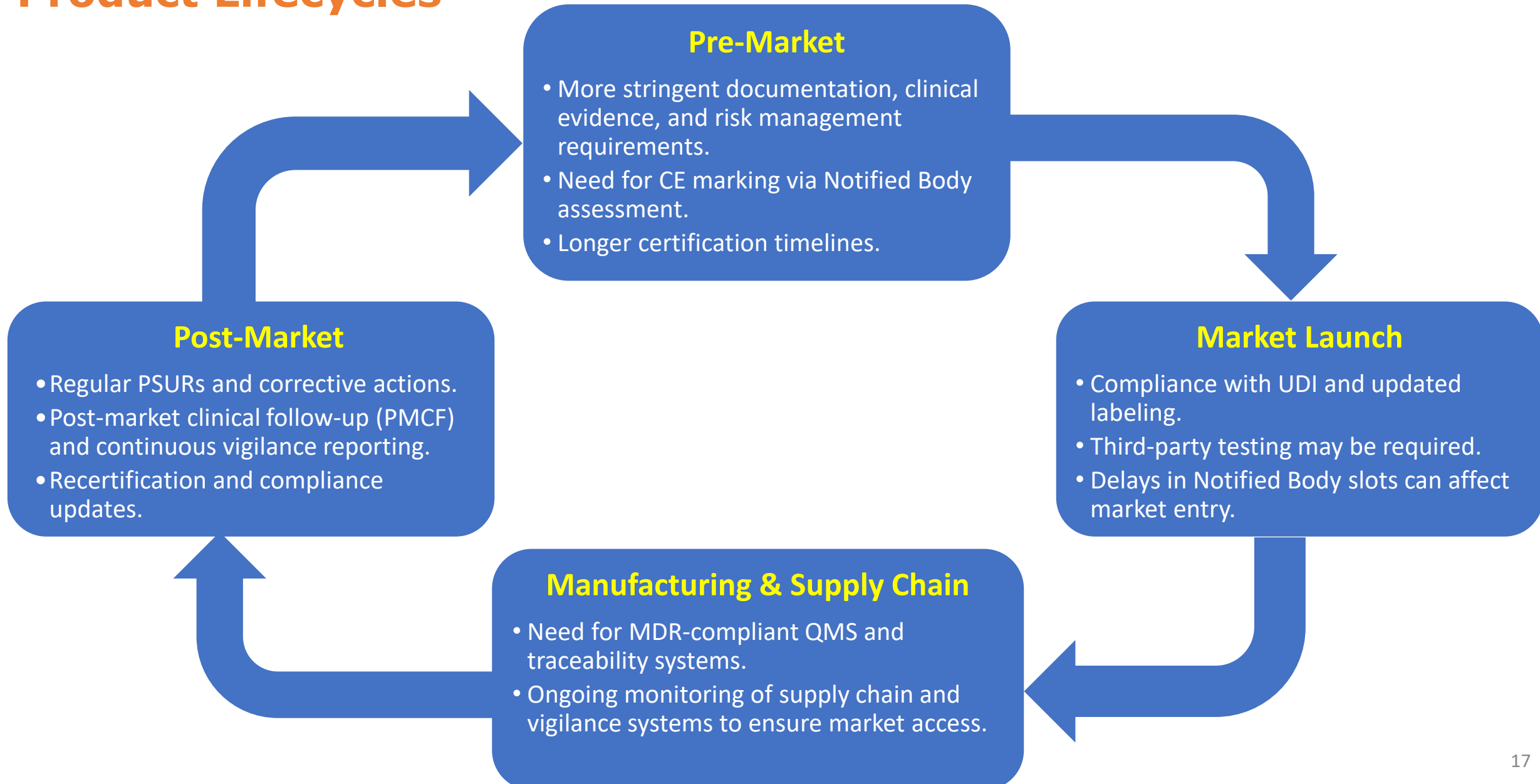
## Stringent MDR Requirements

- Manufacturers must adhere to stringent Medical Device Regulation (MDR) requirements to ensure compliance before market entry.

## Preparation for Challenges

- Establish a vigilance system for reporting adverse events to EUDAMED.

# Evaluating MDR's Market Access Implications Across Product Lifecycles



# Leveraging Compliance for Competitive Advantage

## Market Access

- Timely product certifications with reduced risk of revenue disruption
- Continued access to EU market, one of the largest medical device markets globally
- Positions the organization for faster approvals in other global markets

## Competitive Differentiation

- Builds a trusted brand reputation with clinicians, regulators, and patients
- Fosters smoother interactions with Notified Bodies and auditors

## Data-Driven Decision Making

- Promotes use of clinical evidence and real-world data in product development
- Supports continuous improvement through systematic performance monitoring

## Regulatory Compliance as a Value Proposition

- Enhances brand reputation by meeting stringent standards
- demonstrate their commitment to quality and safety standards.

## Foster Innovation

- Accelerated product development timeline
- Enable efficient use of clinical evidence and user feedback
- Encourages design with clinical evidence and real-world data in mind
- Increased speed to market for next-generation devices

# Key Takeaways

## + Regulatory Challenges

- Navigating EU MDR is essential for medical device manufacturers for market access and compliance.

## + Proactive Strategy

- Early planning strategy minimizes risks and enhances resilience.

## + Product Development Impacts

- Aligning with EU MDR ensures compliant, market-ready devices

## + Optimizing Recertification

- Streamlining recertification cuts time and costs.

## + Post-Market Surveillance

- Strong monitoring ensures safety and performance.

## + Competitive Advantage

- MDR compliance fosters trust and long-term competitive advantage.

**Smith+Nephew**

Life Unlimited