**S+N’s JOURNEY to MDR Compliance**

- **2017**
  - S+N Gap Analysis and scoping for compliance to the regulation
  - EU MDR Program is initiated
  - Resourcing for the program commences

- **2018**
  - Design of business process changes to meet the requirements of the Regulation
  - Strategy for S+N’s EU MDR compliance is endorsed by Notified Bodies
  - Rationalise the portfolio and identify alternatives
  - Early MDD CE renewals to maximise transition period under EU MDR Article. 120

- **2019**
  - IT design and data collection for EUDAMED
  - Persons Responsible for Regulatory Compliance assigned
  - Technical documentation prepared for Class I and Class IR
  - Manufacturer’s QMS updated
  - EU Supply Chain model defined, Economic Operators, single EU Importer
  - Q4 2019 All S+N Notified Bodies are designated under EU MDR

- **2020**
  - Manufacturers Incident Reporting (MIR) from 1 Jan 2020
  - Internal IT systems live & data consolidated
  - Notified Body Reviews for Class I reusable instruments and devices requiring EU MDR Certification begin.
  - CE Mark and submit devices to plan.
  - EU MDR supply chain set up complete.
  - S+N CE Mark Class I Devices to plan.

- **2021**
  - By 26 May 2021 “Date of Application”:
    - Readiness for post-market surveillance, market surveillance, vigilance, registration of economic operators requirements complete.
    - Class I devices CE Marked under EU MDR.

- **2024**
  - By 26 May 2024 all MDD certificates will no longer be valid

- **2025**
  - EU supply chain clear of all MDD devices 5 years post the Date of Application, on 26 May 2025.

**Article 120 Transition Period – Phase in MDR compliant devices**

**2021-2024**
- Continue to Place devices on the market CE Marked under the MDD - up to when MDD certificates expire or 26 May 2024
- CE Mark S+N Class IR, Class IIA, IIB and III devices under the MDR and phase into the EU Supply Chain
- S+N devices supplied in the EU will be CE Marked under EU MDR by 26 May 2024
- Phase out MDD CE Marked devices by 26 May 2025
- EUDAMED data available as required by EU Commission