S+N's JOURNEY to EU MDR Compliance

2017

EU MDR "Entered into Force" 26 May 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

By EU MDR "Date of Application" 26 May 2020:

- Manufacturers Incident Reporting (MIR) from 1 Jan 2020
- Internal IT systems live & data consolidated
- Q1 2020 Notified Body Reviews for Class I reusable instruments and devices requiring EU MDR Certification
- Readiness for post-market surveillance, market surveillance, vigilance, registration of economic operators requirements complete.
- EU MDR supply chain set up will be complete.
- Class I and IR devices CE Marked under EU MDR.

2020-2024

- 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 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

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.

Scope | Design | Implement | Execute | MDD Phase Out

Article 120 Transition Period – Phase in MDR compliant devices