Smith+Nephew'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

- 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

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 - MDD certificates will no longer be valid for devices that are not going to be CE Marked under MDR

2027/2028

MDD Certificates will no longer be valid for devices transitioning to MDR:

- 31 Dec 2027 for Class III and Non WET IIB implants
- 31 December 2028 for all other classes

Scope | Design | Implement | Execute

Article 120 Transition Period – Phase in MDR compliant devices

2021-2028

- Continue to place devices on the market CE Marked under the MDD - up to when MDD certificates expire – Dec 2027/2028
- 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 the transitional deadlines
- EUDAMED data available as required by EU Commission