ABHI

Checklist: Are you ready for Brexit?

Navigating the changes brought about by Brexit requires diligence and coordination. For business continuity, companies should act now to minimise disruption.

Communicate

- ✓ Let your international partners, including those in the EU, know that Britain is still open for business.
- ✓ Be sure to keep partners and your staff informed of your post-Brexit plans and timings.

Supply Chain

- ✓ Address the possible outcomes for each of the future trade models (*single market/customs union/free trade/no deal*) on the source and supply of your components and finished products, including any 'third party' implications.
- Conduct a full supply chain audit using the various scenarios to understand possible cost increases.
- ✓ Using similar scenario-based planning, assess:
 - Customs requirements
 - Market Access and Authorisation
 - Regulatory and Legal implications
 - Staff and Talent Retention
 - Tax Planning and Finance Strategy.

Notified Bodies and Authorised Representatives

- Consider any Brexit implications on product lifecycles and transitions to the Medical Device Regulation from the Medical Device Directive.
- ✓ Speak to your Notified Body (NB) as a matter of urgency, to communicate your Brexit plans and to ensure they have appropriate capacity to manage your products.
- ✓ If you are using a UK NB and selling in the EU, speak to that NB about their contingency planning post-Brexit. You may need to consider migrating your NB to one based in the EU27.
- ✓ If your legal manufacturer is in the UK, you may want to consider a European one or appoint an Authorised Representative in the EU.
- ✓ For UK manufacturers, plan for where your product release will take place.