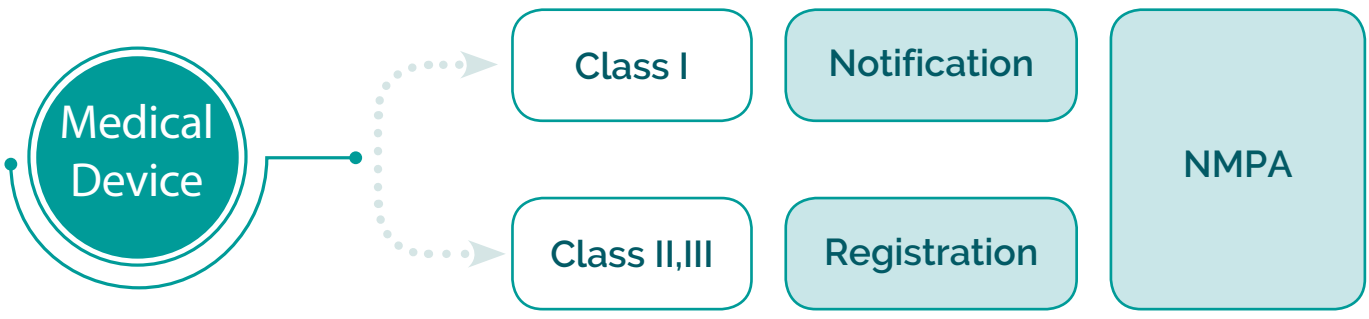
Regulatory Affairs by ELC

Medical device registration in China

Device classifications in China

- Class I Device: The safety and effectiveness of the device can be ensured through routine administration.
- Class II Device: Further control is required to ensure the safety and effectiveness of the device.
- Class III Device: The device is implanted into the human body; used for life support or sustenance; or pose potential risk to the human body, and thus must be strictly controlled in respect to safety and effectiveness.

Imported Registration Pathways



Medical Device registration timelines

Device classification in China	Class I	Class II	Class III
How long you should expect to wait after submission until approval is granted.	<1 week	12-20 months	12-22 months
Validity period for device registrations.	Does not expire	5 years	5 years
Registration renewal should be started this far in advance.	Not Applicable	18-24 months	18-24 months

*Note: The registration timeline above is a conservative estimation that we advise our clients to reserve in order to avoid any delay for the market plan.

How can ELC support your project?

ELC can guide you through the process and support you fulfilling all the regulatory and pharmacovigilance requirements before, during and after approval, offering:

regulatory strategy - dossier preparation, due diligence and gap analysis - BR/BT site in the EEA - translation and readability testing - MA holding – submission management - end-to-end pharmacovigilance

To find out more: info@elc-group.com

Concept to Compliance

www.elc-group.com