SFDA Application Checklist

Importing Medical and IVD Devices to China

*Legal Documents***

	Documents	Content	Format	Complete? (Y/N)
1	Legal registration of the company	1) US Manufacturer: 2891a form	Notarized Copy*	
		2) Europe and other countries: Business license	Notarized Copy*	
		3) If OEM situation exists, must provide documents from both parties.	Notarized Copies*	
2	Certificate of Quality Management System	1) ISO 13485 or ISO 9001 or ISO 46001 Certificate	Notarized Copy*	
3	Marketing Approval Certificate	1) US approval: a) 510(k) Letter	Notarized Copy*	
		b) CFG (certificate to foreign government)	Original with Notarization	
		2) MDD/ IVDD approval: a) EC Certificate	Notarized Copy*	
		b) Declaration of Conformity letter	Original signed	
		3) If above 2 are not available:		
		a) Registration approval certificate	Notarized Copy*	
		b) Free sales certificate	Original with Notarization	
4	Authorization letter	To Registration Agent in China	Original signed	
5	Authorization letter	To the China Registration Agent for Chinese Product Standard Drafting	Original signed	
6	Authorization letter	To appoint a China Agent for adverse event reporting	Original signed	
7	Authorization letter	To appoint an after sales service agent in China	Original signed	
8	Quality guarantee	Letter only	Original signed	
9	Truthful and accuracy self-guarantee letter	Letter only	Original signed	
10	Other documents may required	If OEM situation exists: - OEM contract, black sensitive information or a simple OEM agreement signed by both parties is acceptable.	Notarized Copy Original signed	

Note: * **Notarized documents should have stamp of notary public on each page.**

***The applicable regulatory agency may require additional documentation.*

*Technical Documents***

	Documents	Content	Requirements	Complete? (Y/N)
1	Product Introduction	1) A complete list of the product models, components, and accessories, with brief introduction about the function.	Copy	
		2) Detail information on each model, component, and accessory, its product code/ catalog number, shape, appearance, exact size information.	Copy	
		3) Engineer drawings & circuit diagram	Copy	
		4) Simple production flowchart (for implants and IVD products)	Copy	
		5) List of raw materials and relevant ISO EN or ASTM standards	Copy	
		6) Material certificate from the vendor for each raw material (for implant and IVD product)	Notarized Copy	
2	Specifications, conformed standards and testing report	1) A list of physical, operational and biological specifications of the product & accessories.	Copy	
		2) A list of all applied standards with detail version information.	Copy	
		3) Performance test reports	Copy	
		4) Mechanical test reports	Copy	
		5) Electrical safety test report (IEC 60601-1)	Full report, CB format, Notarized Copy	
		6) EMC report (IEC 60601-1-2)	Copy	
		7) Biocompatibility test report (ISO 10993)	Full report, Copy	
		8) Sterilization test report	Copy	
		9) Stability test report or shelf-life determination test report	Copy	
		10) QC release report for any batch of finish product	Copy	
		11) Specification and testing method of raw materials (for implant products)	Copy	
3	Label information	1) Product brochure, which should have picture of each model of the product and key components and accessories.	3 printed, sign on front page of each	
		2) Package insert		
		3) Operational and Maintenance manual		
		4) Entire set of labels of each model, components and accessories	3 sets, real one or artwork, sign on each	
4	Clinical trial report	1) Clinical trial report or post market clinical literature	Copy, signed on front page	

***The applicable regulatory agency may require additional documentation.*