

Checklist for Import of Medical Device for Veterinary Use in India

Category	Checklist Items	Remarks
Product Name with description		
1. Essentiality and Desirability		
Intended Use	Specific purpose of the device (e.g., diagnosis, treatment, monitoring, surgery etc.).	
Target Species	Animal species intended for the device.	
Market Availability	• Availability of similar devices in the domestic market/Upgraded Model/ apart from existing products. • Highlight any upgraded features or novel aspects/ advantage compared to existing products.	
Is the product marketed elsewhere? If so, provide a list of countries where the product is marketed		
2. Disease Risk Prevention		
Safety Measures	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA).	BIS mandatory for Make in India products.
Infection-Free Certification	Certification confirming that the product and its components are free from infectious agents (e.g., bacteria, viruses, fungi) and comply with BSE/TSE-free requirements.	Supplier must provide certification if uses any animal origin product during manufacturing of the device.

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Associated risk of contamination/spread of infection during use		
3. Regulatory Compliance		
International Certification	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA or any other reputed international organization).	BIS mandatory for Make in India products.
Adherence to Standards	Compliance with international safety standards (e.g., ISO, WOH, CE, FDA Electro Technical Commission (IEC), or other pharmacopeia standards.	
4. Technical Specifications		
Documentation	i. Complete technical dossier (design, composition, operational guidelines) ii. Safety and Effectiveness Studies iii. Ensure the device performs as intended, with data on accuracy, precision, and sensitivity iv. Guidelines for disposal after use	
5. Environmental and Ethical Considerations		
Environmental Impact	Guidelines for disposal of hazardous waste (if any)	
Executive Summary: A summary of key supporting documentation. Every Please provide an introductory text or narratives to help connect the submitted documents. Any exceptions or unusual circumstance which the firm wishes to highlight, specific to the device or application, should be mentioned in the Executive Summary		