

Central Drug Standard Control Organization
Directorate General of Health Services
Office of Drugs Controller General (India)
(Medical Device Division)

Checklist for Pre-screening of Applications for Grant of Import license in Form 10 for Non-Notified Diagnostic Kits:

Name of the firm: _____ **Date:** _____

TR-6 Challan No: _____ **Date:** _____ **Ref.No:** _____

S. No.	Administrative/Legal Documents	Status	
		Yes	No
1.	Covering Letter, with email id of authorized signatory- Purpose should be clearly mentioned with page number and Index.		
2.	Form-8 and product list along with specific intended uses, duly signed and stamped by the Indian agent along with name and designation of authorized signatory		
3.	Duly notarized Form 9 duly signed and stamped by the authorized signatory of manufacturer from country of origin.		
4.	Requisite Fee Rs 1000/- for one proposed product and Rs. 100/- for each additional product.		
5.	Duly notarized and valid copy of Free Sale certificate or Certificate to Foreign Government issued by National Regulatory Authority from country of origin mentioning name and address of both legal and actual manufacturer.		
6.	Notarized and valid copy of whole sale license or manufacturing license in respect of Indian Agent		
7.	Duly notarized, from country of origin, and valid copy of ISO 13485 certificate in respect of Actual manufacturer		
8.	Performance Evaluation Reports from National Accredited Labs of India for 3 batches for products intended for Malaria, Dengue,		

	Chikungunya, Syphilis, Typhoid, Tuberculosis, and Cancer markers.		
9.	Product inserts, Labels, COA for the proposed products		
10.	Soft copy of product list along with specific intended uses.		

Signature of the Reviewer with Date

Accepted /Returned due to incomplete application