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 Registration Certificate to Notified Diagnostic kits in Form-41

Name of the firm:_____ Date: _____

TR-6 challan No:_____ Date:_____ Ref.No:_____

S. No.	Administrative /Legal Documents.	Status	
		YES	NO
1.	Covering Letter-Purpose should be clearly mentioned with page number and Index.		
2.	Application in Form-40		
	• Duly signed & stamped by the Indian Agent		
	• Name of the Medical Device(s) to be registered		
	• Name & Address of Authorized Agent in India		
	• Names & Address of Manufacturer & its Factory Premises		
3.	TR 6 Challan		
	• Fees paid (1500 USD for site & 1000 USD for each product):		
	• Head to Fees Deposited ("0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines)		
	• Should indicate the name and address of the premises to be registered		
	• Realisation Stamp		
4.	Power Of Attorney(Original)		
	• Executed & authenticated either in India before a First class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country (original copy)		
	• Name of the manufacturer & its manufacturing site as per Form-40 along with the name of the Device		
	• Name and address of the Indian Agent		
	• Name of the Proposed Products		
	• Duly signed, dated with name & designation of the signatory by both Indian agent & the manufacturer		
5.	Copy of valid Wholesale Licence or Manufacturing Licence of the Indian Agent		
6.	Schedule DI &Undertaking duly signed, stamped & dated with name & designation of authorized signatory		
7.	Schedule DII &Undertaking duly signed, stamped & dated with name & designation of authorized signatory		
8.	Notarized & Valid Copies of (As applicable wrt FSC) (a) Quality Management System Certificate (ISO 13485) (b) Full Quality Assurance Certificate (c) CE Design Certificate		

	(d) Declaration of Conformity		
9.	Notarized & Valid copy of Free Sale Certificate from the country of origin		
10.	Notarized/Apostilled and Valid copy of Free Sale Certificate from any one of the GHTF member countries		
11.	Notarized Plant Master file		
12.	Notarized Device Master file		
13.	Performance Evaluation Report from NIB, Noida		
14.	The report of evaluation in details conducted by National Control Authority of country of origin		

Accepted /Returned due to incomplete application

Signature of the Reviewer with Date