

# 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 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		
	<ul style="list-style-type: none"><li>Duly signed &amp; stamped by the Indian Agent</li></ul>		
	<ul style="list-style-type: none"><li>Name of the Medical Device(s) to be registered</li></ul>		
	<ul style="list-style-type: none"><li>Name &amp; Address of Authorized Agent in India</li></ul>		
	<ul style="list-style-type: none"><li>Names &amp; Address of Manufacturer &amp; its Factory Premises</li></ul>		
3.	TR 6 Challan		
	<ul style="list-style-type: none"><li>Fees paid (1500 USD for site &amp; 1000 USD for each product):</li></ul>		
	<ul style="list-style-type: none"><li>Head to Fees Deposited ("0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines)</li></ul>		
	<ul style="list-style-type: none"><li>Should indicate the name and address of the premises to be registered</li></ul>		
	<ul style="list-style-type: none"><li>Realisation Stamp</li></ul>		
4.	Power Of Attorney(Original)		
	<ul style="list-style-type: none"><li>Executed &amp; 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)</li></ul>		
	<ul style="list-style-type: none"><li>Name of the manufacturer &amp; its manufacturing site as per Form-40 along with the name of the Device</li></ul>		
	<ul style="list-style-type: none"><li>Name and address of the Indian Agent</li></ul>		
	<ul style="list-style-type: none"><li>Name of the Proposed Products</li></ul>		
	<ul style="list-style-type: none"><li>Duly signed, dated with name &amp; designation of the signatory by both Indian agent &amp; the manufacturer</li></ul>		
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		

Accepted/Returned due to incomplete application

Signature of the Reviewer with Date