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

CHECKLIST FOR ACCEPTABILITY OF APPLICATION PERTANING TO GRANT OF PERMISSION TO IMPORT OR MANUFACTURE NEW MEDICAL DEVICE GOING TO BE INTRODUCED FOR THE FIRST TIME IN THE COUNTRY FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

Name of the Firm:_____**Date:**_____

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

S.No.	**Documents required to be submitted**	**Status**	
		Yes	**No**
1.	Whether proposed device is notified Medical Device under Drugs and Cosmetics Act & Rules		
2.	**Covering Letter:** Application for permission to import or manufacture new drugs for sale or to undertake clinical trials- Purpose should be clearly mentioned with page numbers and index		
3.	Application in Form 44 should be complete in all respect and signed & stamped by the authorized person of the firm with name and designation. It should include following information: a. Name of the Applicant b. Name of the Medical Device c. Composition/Accessories d. Intended Use etc.		
4.	Treasury Challan of Rs.50,000/- / 15,000/- and should mention the name of the New Device including correct head of the account payable at, bank clearance, etc		
5.	**Protocol:** the contents of Protocol should be as follows:		

i.	Title page		
ii.	Table of content		
iii.	Study Objective(s) (primary as well as secondary) and their logical relation to the study design		
iv.	Study design		
v.	Study population		
vi.	Subject Eligibility- Inclusion Criteria and Exclusion Criteria		
vii.	Study Assessment		
viii.	Study Treatment		
ix.	Adverse Events		
x.	Ethical Consideration		
xi.	Study Monitoring and Supervision		
xii.	Investigational Product Management		
xiii.	Data Analysis		
6.	Undertaking by the Investigator: This shall include all the details / elements as mentioned in the Appendix VII of Schedule-Y.		
7.	Informed consent documents (patient information sheet, informed consent form etc.) as per Appendix V of Schedule-Y should mention the following: ***"In case of study related injury or death M/s. (NAME OF THE COMPANY) will provide complete medical care along with compensation for the injury or death"***		
8.	Case Record Form		
9.	Justification for conducting the study in India <u>Type of Study:</u> a. Feasibility b. Pilot Study c. Pivotal Study		
10.	Details of Pre Clinical Study		
11.	Details of Previous Clinical Study conducted pertaining to said product in other countries		
12.	Published Literature Review / Clinical Evaluation Reports		

13.	Protocol Approval Status of the proposed study in GHTF and other participating Countries, if any		
14.	Ethics Committee approvals if available (Ethics Committee should be of same area where the site is located).		
15.	Investigators Brochure		
16.	Technical Documents:-Specimen Copy of Labels, IFU's & Package Insert:- (if the device is marketed in any country)		

Signature of the Reviewer with Date

Accepted / Returned due to Incomplete Application