Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.1. Pre-Screening checklist for acceptability of applications for Grant of Registration Certificate/Re-Registration Certificate in Form-41 for Medical Devices

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick (√)	Pg. No.	Annexure
	PART -A			
1.	Covering Letter-Purpose should be clearly mentioned with Page No. and Index.			
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Duly filled and signed Application in Form-40			
4.	Fee in TR6 Challan of USD 1500 for each site and USD 1000 for each product equivalent to INR in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
5.	Apostilled Power of Attorney (Original) issued by the manufacturer to Indian agent			
6.	Notarized copy of valid Wholesale Licence or Manufacturing Licence of the Indian Agent			
7.	Schedule DI & Undertaking duly filled, signed, stamped & dated with name & designation of the manufacturer/Indian agent.			
8.	Schedule DII duly filled, signed, stamped & dated with name & designation of the manufacturer/Indian agent.			
9	**Regulatory Certificates :**			
9.1	Duly apostilled/notarized copy of Free Sale Certificate/Marketing Authorization of the product from National Regulatory Authority of country of origin (if any)			
9.2	Duly apostilled/notarized copy of Free Sale Certificate Marketing Authorization of the product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan, Australia.			
10	Duly notarized valid copies of Quality Certificate in respect of the legal and actual manufacturing site (s) (wherever applicable) (a) Certificate supporting Quality Management System (b) Full Quality Assurance Certificate / CE Type Examination Certificate/ CE Product Quality Assurance (c) CE Design Certificate (d) Declaration of Conformity.			
11	Notarized IFU, Pack Insert of the applied devices.			
12	Notarized Labels of the device as per Rule 109 A of D&C Rules.			
	Part- B			
13	• Notarized Plant Master file from the Manufacturer • Duly notarized undertaking from the manufacturer for no change in Plant Master File (in case of re-registration)			
14	• Notarized Device Master file from the Manufacturer			

	• Duly notarized undertaking from the manufacturer for no change in Device Master File (In case of re-registration)			
17	Notarized Undertaking regarding complaints received w.r.t "Not of Standard Quality" of the proposed products during last three years (In case of re-registration)			
18	Duly notarized PMS Study Report for last three years (In case of re-registration)			
18.1	Detail of AEs/SAEs/Death/Recall/complaints of the proposed products reported globally along with protocol for investigation of root cause and CAPA taken by the manufacturer (if any)			
18.2	Detail of AEs/SAEs/Death/Recall/complaints of the proposed products during the last three years in India along with protocol for investigation of root cause and CAPA taken by the manufacturer (if any)			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) …….mentioned above.

Signature: ……..
Name of the Reviewer:…..…….
Date:…….……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.2. Pre-Screening checklist for acceptability of applications for Grant of Import License in Form-10 for notified medical devices /In-vitro Diagnostics

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1.	Covering Letter-Purpose should be clearly mentioned with page number and Index.			
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Form-8 duly Signed & Stamped by applicant along with name & designation of the Authorized Signatory			
4.	Form-9 duly Signed & Stamped by Indian Agent along with name & designation of the Authorized Signatory or duly appostilled/ notarized if signed & stamped by the Manufacturer			
5.	Notarized copy of Wholesale Licence or Manufacturing Licence of the Indian Agent			
6.	Original T/R Challan for Requisite Fee **Rs.1000** for One Proposed Device and **Rs.100** for each additional Device in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
7.	Copy of Registration Certificate in form-41			
8.	Documents as stated in Registration Certificate (In case of conditional certificate)			
10.	Notarized Labels of the device as per Rule 109 A of Drugs & Cosmetics Rules).			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) ……mentioned above.

Signature: ……..
Name of the Reviewer:…….
Date:……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.3. Pre-Screening checklist for acceptability of applications for Grant of Test License in Form-11 for small quantity of medical devices

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexures
1.	Covering Letter clearly mentioning the type of test to be performed by using the proposed products- Purpose should be clearly mentioned with page number and Index.			
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Duly filled Form-12 Signed & Stamped by the authorized signatory of the Applicant, mentioning the name & address of the manufacturer, name and address of the testing places and. Name of the product and pack size (number of test per pack) , as per Drugs And Cosmetic Acts And Rules			
4.	TR-6 Challan, Fee paid Total Amount (Rs.100 for One product and Rs.50 for each additional product) in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
5.	Utilization breakup along with Justification for the proposed quantity of each of the product			
6.	Product Inserts, Label of the proposed product			
7.	Testing protocol of the proposed product (if any)			
8.	Valid copy of manufacturing license/wholesale license(if any)			
9.	Undertaking stating that the proposed kits are Not For Commercial Purpose			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..……. **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) …….mentioned above.

Signature: ……..
Name of the Reviewer:…….
Date:…….

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.4. Pre-Screening checklist for acceptability of applications for application pertaining 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.	Administrative/Legal /Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexures
1	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
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.			
4.	Treasury Challan of Rs.50,000/- / 15,000/- and should mention the name of the New Device in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
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 Type of Study: 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)			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..……. **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) …….mentioned above.

Signature: ……..

Name of the Reviewer:…..…….

Date:…….…….

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.5. Pre-Screening checklist for acceptability of applications for Extension in shelf life of the already Registered Product

Name of the firm: _____ Date: _____

S. No.	Administrative/Legal Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1	Covering Letter-Purpose should be clearly mentioned with page number and Index.	☐		
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Copy of Registration certificate mentioning the name of the product along with approved shelf life of the devices.	☐		
4	Certificate of Approval of extension in shelf life issued by National Regulatory Authority in country of origin. (In case where formal approvals are not provided by NRA, Letter submitted to inform NRA/ notified body)	☐		
5.	List of the countries where product with proposed extension in shelf life approved along with regulatory documents.	☐		
6.	Stability Data including Stability protocol (Accelerated or Real Time) stability test reports as per extension in shelf life proposed.	☐		

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..……. **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) ……mentioned above.

Signature: ……..

Name of the Reviewer:…..…….

Date:…….…….

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.6. Pre-Screening checklist for acceptability of applications for Additional Indication of the already Registered Product

Name of the firm: _____ Date: _____

S. No.	Administrative/Legal Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1.	Covering Letter-Purpose should be clearly mentioned with page number and Index.	☐		
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm	☐		
3.	Copy of Registration certificate mentioning the name of the product along with indication approved earlier	☐		
4.	Certificate of Approval of additional indication issued by National Regulatory Authority in country of origin	☐		
5.	Published data/detail of the study carried out for the additional indication	☐		
6.	List of the countries where product with additional indication approved along with regulatory documents	☐		
7.	Notarized revised and existing IFU's/Package Inserts in respect of additional indication of the proposed product	☐		

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..……. **E-mail**:……

Office Use Only:

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Signature: ……..
Name of the Reviewer:…..…….
Date:…….……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

A.7. Pre-Screening checklist for acceptability of applications for further Clarification in respect of the Product

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

S. No.	Administrative/Legal Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1.	Covering Letter-Purpose should be clearly mentioned with page number and Index.	☐		
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm	☐		
3.	Detail Product description along with material of construction, intended use, Product specification, product literature, package inserts alongwith a sample	☐		
4.	Regulatory status of the said product in country of origin	☐		
5.	Regulatory certificates in respect of said product	☐		

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

Office Use Only:

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Signature: ……..
Name of the Reviewer:…..…….
Date:…….……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

B.1. Pre Screening checklist for acceptability of applications for Grant of Registration Certificate/Re-Registration Certificate of Notified in vitro Diagnostic Kits/Reagents in Form 41

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick (√)	Pg. No.	Annexure
	PART –A			
1.	Covering Letter-Purpose should be clearly mentioned with Page No. and Index.			
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Duly filled and signed Application in Form-40			
4.	Fee in TR6 Challan of USD 1500 for each site and USD 1000 for each product equivalent to INR in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
5.	Apostilled Power of Attorney (Original) issued by the manufacturer to Indian agent			
6.	Notarized copy of valid Wholesale Licence or Manufacturing Licence of the Indian Agent			
7.	Schedule DI & Undertaking duly filled, signed, stamped & dated with name & designation of the manufacturer/Indian agent.			
8.	Schedule DII duly filled, signed, stamped & dated with name & designation of the manufacturer/Indian agent.			
9	**Regulatory Certificates :**			
9.1	Duly Apostilled/notarized copy of Free Sale Certificate/Marketing Authorisation of the product from National Regulatory Authority of country of origin (if any).			
9.2	Duly Apostilled/notarized copy of Free Sale Certificate Marketing Authorisation of the product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan, Australia.			
10	Duly Apostilled/notarized valid copies of Quality Certificate in respect of the legal and actual manufacturing site (s) (wherever applicable) (e) Certificate supporting Quality Management System (f) Full Quality Assurance Certificate /CE Production Quality Assurance Certificate/ CE Type Examination Certificate/ CE Product Quality Assurance (g) CE Design Certificate (h) Declaration of Conformity.			
11	Notarized IFU, Pack Insert of the applied devices.			
12	Notarized Labels as per Rule 109 A of Drugs & Cosmetics Rules			

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

13.	Performance Evaluation Report of Products (HIV, HCV, HBV & Blood grouping sera) from NIB, Noida for three consecutive batches. If NIB do not have facility for testing , PER from other institution will be accepted.			
	Part- B			
14	• Notarized Plant Master file from the Manufacturer • Notarized undertaking from the manufacturer for no change in Plant Master File (in case of re-registration)			
15.	• Notarized Device Master file from the Manufacturer • Notarized undertaking from the manufacturer for no change in Device Master File (In case of re-registration)			
16.	The report of evaluation in details conducted by National Control Authority of the country of origin.			
17.	Information as per Annexure B(HIV, HCV, HBV & Blood Grouping Sera) of Schedule DII			
20.	Notarized Undertaking regarding complaints received w.r.t "Not of Standard Quality" of the proposed products during last three years (In case of re-registration)			
21.	Duly notarized PMS Study Report for last three years (In case of re-registration)			
21.1	Detail of AEs/SAEs/Recall/complaints of the proposed products reported globally along with protocol for investigation of root cause and CAPA taken by the manufacturer (if any)			
21.2	Detail of AEs/SAEs/Recall/complaints of the proposed products during the last three years in India along with protocol for investigation of root cause and CAPA taken by the manufacturer (if any)			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..……. **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) …….mentioned above.

Signature: ……..

Name of the Reviewer:…..……

Date:…….……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

B.2. Pre-Screening checklist for acceptability of applications for Grant of Import License in Form-10 for Non-notified in vitro Diagnostic Kits.

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1.	Self-attested copy of Authorization Letter issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name and designation of the person authorized to sign (along with the name and address of the firm) legal documents such as Form 8, Form 9 etc.)			
2.	Form-8 duly Signed & Stamped by applicant along with name & designation of the Authorized Signatory			
3.	Form-9 duly Signed & Stamped by Indian Agent along with name & designation of the Authorized Signatory or duly, if signed & stamped by the Manufacturer			
4.	Notarized & copy of Wholesale Licence or Manufacturing Licence of the Indian Agent			
5.	Original T/R Challan for Requisite Fee **Rs.1000** for One Proposed Device and **Rs.100** for each additional Device in A/C Head "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines			
6.	**Regulatory Certificates :**			
6.1	Duly Apostilled/notarized copy of Free Sale Certificate/Marketing Authorization of the product from National Regulatory Authority of country of origin or Duly Apostilled/notarized copy of Free Sale Certificate Marketing Authorization of the product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan, Australia.			
6.2	Duly Apostilled/notarized valid copies of Quality Certificate in respect of the legal and actual manufacturing site (s) (wherever applicable) (a) Certificate supporting Quality Management System (b) Full Quality Assurance Certificate /CE Production Quality Assurance Certificate/ CE Type Examination Certificate/ CE Product Quality Assurance (c) CE Design Certificate (d) Declaration of Conformity.			
7.	Duly notarized, from country of origin, copy of Quality Management System Certificates in respect of Actual manufacturer.			
8.	Performance Evaluation Reports (PER) from NABL			

	approved laboratory for 3 batches for products intended for Malaria, Tuberculosis, Dengue, Chikungunya, Syphilis, Typhoid and Cancer markers.			
9.	In case of Blood Glucose test strips, PER from NIB, NOIDA. If NIB do not have facility for testing, PER from other institution will be accepted.			
10.	NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits			
11.	NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits			
12.	NOC from DG, ICMR, In case of influenza Kit			
13.	Notarized Copies of : i) Product inserts, ii) Labels as per Rule 109A, iii) Certificate of analysis (COA) for the proposed products.			
14.	A Copy of import License in form-10 (if the application is for renewal/ Endorsement)			
15.	Soft copy of product list along with specific intended uses (Word format).			
16.	Correlation chart with respect to products list mentioned in Form 8, Form 9 and FSC submitted			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

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Signature: ……..

Name of the Reviewer:…..……

Date:…….……

Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

B.3. Pre-Screening checklist for acceptability of applications for Grant of Test License in Form-11 for in-vitro diagnostic Kits/reagents:

Name of the firm: _____ Date: _____

TR-6 Challan No:_____Date:_____Ref: No:_____

S. No.	Administrative/Legal /Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1.	Covering Letter-Purpose should be clearly mentioned with page number and Index.			
2.	Self-attested copy of authorization letter to the person issued by the Director/Company Secretary/Partner of the Indian Agent firm			
3.	Form-12 duly Signed & Stamped by the authorized signatory of the Applicant, mentioning the name & address of the manufacturer, name and address of the testing places and. Name of the product and pack size			
4.	TR-6 Challan, Fee paid Total Amount(Rs.100 for One product and Rs.50 for each additional product)			
5.	Utilization breakup along with Justification for the proposed quantity of each of the product			
6.	Copy of Product Insert or Label of the proposed product			
7.	Testing protocol of the proposed product (if any)			
8.	Valid copy of manufacturing license/wholesale license(if any)			
9.	Undertaking stating that the proposed kits are Not For Commercial Purpose			
10.	Valid Copy of NABL accreditation certificate of testing laboratory(wherever applicable)			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

Office Use Only:

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Signature: ……..

Name of the Reviewer:…..……

Date:…….……