CHECKLIST FOR DOCUMENT ACCEPTING OF CONSOLIDATED NEW MEDICAL DEVICE APPLICATIONS

National Medicines Regulatory Authority, Sri Lanka

Local Category A ☐ Local Category B ☐ Foreign ☐	
For foreign applications	FMSA+PRD application/Non reliance ☐ FMSA+PRD application/ reliance ☐ PRD application/ Non reliance ☐ PRD application/ reliance ☐

Generic Name of the device *(according to the GMDN)*	
Brand Name	
Manufacturer	
Local Agent	

All following documents are mandatory for accepting application. At the accepting point, only check the availability of such documents.

1.General Section

1.1 Common Administrative documents required

Type of document	Page number	Availability (Yes/No)
1. Letter of Authorization (LOA) from the legal manufacturer		
2. Declaration letter confirming the type of dossier from the local agent.		
3. Declaration letter intention to submit the samples upon request of the authority		
4. Agency transfer letter issued by NMRA (If applicable)		
1.2 Common Technical documents required		
7. Valid Free Sale Certificate (FSC)		
8. Copy of GMP report issued by the NMRA for local manufacturers (If applicable)		

9. Copy of foreign manufacturing site approval issued by NMRA or NMRA product registration certificate as evidence		
10. ISO quality management system certificate (ISO 13485:2016/2021, ISO 9001:2015)		
11. Foreign country registration evidence documents (Product registration certificate or FSC issued by the relevant health authority)		
2. **Section 01 - Documents required for FMSA**		
12. Application form for FMSA		
13. Copy of Business Registration of the authorized local agent		
14. Copy of Board of Directors' Registration of the authorized local agent (if applicable)		
15. Company Registration (Form 01/15/40)		
16. Declaration letter from manufacturer stating the local representation, manufacturing site status, readiness for inspection and, accuracy of submitted documents		
17. Declaration letter from regulatory Pharmacist/qualified person stating that information given in this application is correct.		
18. Declaration letter from legal manufacturer mentioning the details of other manufacturing sites belong to the legal manufacturer and which are not included in the application		
19. Consent Letter from local agent to withdraw the application when the NMRA noticed duplications		
20. Site Master File		
21. List of exporting countries		
3. Section 02 - Documents required for PRD		
22. Application form for Sample Import License (Schedule IV, form C)		
23. Application Form (Schedule I Form A)		
24. Application Form (Schedule I Form B)		
25. Device Details from the manufacturer		
26. Manufacturer declaration of conformity/ EC full quality assurance system certificate/ EU quality management system certificate or manufacturer EC declaration of conformity		

27. ***If CE marked medical devices;*** EC design examination certificate (if applicable)		
28. Summary Technical Documentation (STED)		
29. Essential Requirement Check list		
30. Risk Analysis Report		
31. Certificate of Analysis (COA)/ Finished product test report/ final product inspection test report		
32. Stability protocol with data report (if applicable)		
33. ***For Sterile medical devices;*** 33.1. Sterility report		
33.2 Sterilization validation protocol with report		
33.3 EO residual test data for EO sterilized products		
33.4 Package integrity data report		
34. Biological evaluation report (if applicable)		
35. Clinical evaluation test report (if applicable)		
36. ***For active medical devices;*** 36.1 For active medical devices; Electrical safety data and Electromagnetic Compatibility data report (Eg: IEC standard)		
37. ***For medical devices with measuring function;*** 37.1 Certification on medical devices, metrology or equivalent		
38. ***For radiation emitting medical devices;*** 38.1 Atomic Energy Authority Approval certificate		
39. Third party test report (If applicable)		
40. Software verification and validation report (If applicable)		
41. ***For devices containing biological material;*** 41.1 A list of all materials used in the medical device and its manufacturing process that come from animal, human, microbial, or genetically modified (recombinant) sources		
42. Bovine Spongiform Encephalopathy (BSE) report (If applicable)		
43. Product labels (Original/ artwork/ draft)		

44. Product catalogue or brochure		
45. For IVD use medical device Performance evaluation test report		
46. Instructions For Use (IFU) (If applicable)		
47. Patient Information Leaflet (In 03 languages for the point of care medical devices		
48. List of standard accessories, reagents and consumables (If applicable)		

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Signature of the applicant
Name:
Designation:
Date:

……..…….
Signature of the Accepting officer (NMRA)
Name:
Designation:
Date:

Remarks:

1. Letter of Authorization should be addressed to CEO/NMRA and product range should be mentioned clearly.
2. Free Sale Certificate should be issued by relevant health authority of government body of the country of origin.
3. Indicate in the remark column, if specimens are artworks (For machineries)