CHECKLIST FOR DOCUMENT ACCEPTING OF MEDICAL DEVICE APPLICATION

National Medicines Regulatory Authority, Sri Lanka

Application type : Local category A ☐ Local category B ☐ Foreign ☐

New ☐ RR ☐

Application No:	Date of submission:
Receipt attached & Number written : Yes/No	Page numbered both ways : Yes/No

Approved Name	
Brand Name	
Manufacturer	
Local Agent	

All Following Documents are Mandatory for Accepting Application. At the Accepting Point Only Check the Availability of Such Documents.

Document	Page Numbers	Availability	Remarks
1. Comprehensive table of content (Index)		Yes/No	
2. Application form signed by authorized person (schedule 1 Form A / Form B)		Yes/No	
3. Letter of authorization from legal manufacturer		Yes/No	
4. Copy of foreign manufacturing site approval letter (If applicable)		Yes/No	
5. Copy of GMP report issued by NMRA for local products		Yes/No	
6. Copy of sample license (for New)/ previous registration (for RR)		Yes/No	
7. Free Sale certificate			
8. Hygienic certificate (If applicable)		Yes/No	
9. ISO certificate		Yes/No	
10. EC certificate		Yes/No	
11. EC declaration of conformity (If applicable)			
12. EC design examination certificate (If applicable)		Yes/No	

13. COA /Finished product inspection report		Yes/No	
14. Stability report with protocol/ declaration of shelf life (If applicable)		Yes/No	
15. Sterility report (If applicable)		Yes/No	
16. Sterilization validation report with protocol (If applicable)		Yes/No	
17. EO residual test report (If applicable)		Yes/No	
18. Biological evaluation report (If applicable)		Yes/No	
19. Electrical safety data report (If applicable)		Yes/No	
20. Performance evaluation test report for IVD (If applicable)		Yes/No	
21. Risk management report		Yes/No	
22. Third party test report (If applicable)		Yes/No	
23. Bovine Spongiform encephalopathy report (If applicable)		Yes/No	
24. Atomic energy authority approval for radiation emitting device		Yes/No	
25. List of countries with evidence for other country registration		Yes/No	
26. List of standard accessories, spare parts, reagent & consumables (If applicable)		Yes/No	
27. Instruction for use (IFU) for IVD kits		Yes/No	
28. Product labels-Original/ Artwork/ Draft & product catalogue		Yes/No	

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Signature
Name:
Designation of the applicant:
Date:

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Signature
Name:
Designation of the accepting officer:
Date:

Remarks:

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