CHECKLIST FOR DOCUMENT ACCEPTING OF RE-REGISTRATION OF MEDICAL DEVICES

National Medicines Regulatory Authority, Sri Lanka

Local Category A ☐	Local Category B ☐	Foreign ☐

Generic Name of the device	
Brand Name	
Manufacturer	
Local Agent	

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

Type of document	Page number	Availability (Yes/No)
1. Letter of Authorization (LOA) from the legal manufacturer		
2. Valid Free Sale Certificate(FSC)/Hygienic Certificate		
3. Copy of GMP report and/or manufacturing license issued by the NMRA for local manufacturers (If applicable)		
4. Copy of Previous NMRA product registration certificate		
5. Agency transfer letter issued by NMRA (If applicable)		
6. ISO quality management system certificate (ISO 13485:2016/2021, ISO 9001:2015)		
7. Foreign country registration evidence documents (Product registration certificate or FSC issued by the relevant health authority)		
8. Application Form (Schedule I Form A)		
9. Application Form (Schedule I Form B)		
10. Device Details from the manufacturer (As per the NMRA format)		
11. Manufacturer declaration of conformity, EC full quality assurance system		

certificate/ EU quality management system certificate or manufacturer EC declaration of conformity (if applicable)		
12. EC design examination certificate (if applicable)		
13. Summary Technical Documentation (STED)		
14. Essential requirement checklist		
15. Risk Analysis Report		
16. Certificate of Analysis (COA)/ Finished product test report/ final product inspection test report		
17. Stability protocol with data report (if applicable)		
18. ***For Sterile medical devices;*** 18.1. Sterility report		
18.2 Sterilization validation protocol with report		
18.3 EO residual test data for EO sterilized products		
18.4 Package Integrity		
19. Biological evaluation report (if applicable)		
20. Clinical evaluation test report (if applicable)		
21. ***For active medical devices;*** 21.1 Certification to electrical safety data		
22. ***For medical devices with measuring function;*** 22.1 Certification on medical devices, metrology or equivalent		
23. ***For radiation emitting medical devices;*** 23.1 Atomic Energy Authority Approval certificate		
24. Third party test report (If applicable)		
25. Software verification and validation test report		
26. ***For devices containing biological material;*** 26.1 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		
27. Bovine Spongiform Encephalopathy (BSE) (If applicable)		
28. Product labels (Original or photographs)		

29. Product catalogue or brochure		
30. For IVD use medical device Performance evaluation test report		
31. Instructions For Use (IFU) (If applicable)		
32. Patient Information Leaflet (In 03 languages for the point of care medical devices)		
33. 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.