CHECKLIST FOR DOCUMENT ACCEPTING OF MEDICAL DEVICE SAMPLE IMPORT LICENSE APPLICATION

National Medicines Regulatory Authority, Sri Lanka

Application No: Date of Submission:

Product Official Name	
Product Brand Name	
Name of the Manufacture	
Name of the Local Agent	

Required Documents

	Document	Page Numbers	Availability	Remark
1.	Application form for each product (Form C Schedule IV)		Yes/ No	
2.	Business Registration Certificate		Yes/ No	
3.	Letter of authorization		Yes/ No	
4.	Free Sale Certificate		Yes/ No	
5.	ISO 13485 (Not mandatory for NMRA approved site)		Yes/ No	
6.	Existing registration certificate issued by NMRA/FMSA approval by the NMRA		Yes/ No	
7.	Product catalogue/ Brochure		Yes/ No	
8.	Sri Lanka Atomic energy authority approval for radiation emitting device		Yes/ No	

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Signature Signature

Name: Name:

Designation of the applicant: Designation of the accepting officer:

Date: Date:

Remarks:

1. Letter of authorization should be address to CEO/ NMRA and should be signed by the authorized person

2. Free sale certificate should be issued by relevant health authority or government body of the country of origin