NATIONAL MEDICINES REGULATORY AUTHORITY

SRI LANKA.
120, Norris Canal Road, Colombo 10, Sri Lanka.

Application form for Waiver of Registration OF A MEDICAL DEVICE

For government institution ☐

For private institution ☐

1. Applicant Detail	
1.1 Name of the applicant	
1.2 Address of the applicant	
1.3 Telephone no.	
1.4 E – mail	

2. Details of the Product	
2.1 Official/Common name of the product	
2.2 Brand name (if applicable)	
2.3 Model (if applicable)	
2.4 Sizes (if applicable)	
2.5 Quantity	
2.6 Total cost	

3. Details of Manufacturer	
3.1 Name of the legal manufacturer & country	

3. 2 Name of physical manufacturer & country (If applicable)	

4. Details of the distributor (if applicable)	
4.1 Name of the Distributor	
4.2 Country	

5. Detail of local agent (If applicable)	
5.1 Name	
5.2 Address	
5.3 Contact detail	

6. Importer Detail (If applicable)	
6.1 Name	
6.2 Address	
6.3 Contact detail	

7. Past history of issued WOR of particular item (if applicable)	
7.1 WOR number (Letter No)	
7.2 Date of issue	

8. Reason for WOR (tick √)	
8.1 Delay NMRA Registration Short expiry of NMRA registration	☐
8.2 Registered sources not quoted	☐

8.3 Lowest price than registered item ☐

8.4 Registered product not complied with tender specification ☐

8.5 Manufacturer's name changed ☐

8.6 Government to Government agreement ☐

8.7 No registered sources ☐

8.8 Short shelf life of the product ☐

8.9 Research ☐

8.10Donation

8.11 Other (If so reason should be mentioned) ☐

Remarks

9. Sample evaluation detail (if applicable)	
9.1Name of evaluator	
9.2 Designation	
9.3 Institution	

10. NMRA Registration Status (if applicable)	
10.1 Application No	
10.2 Date of submission	
10.3 Certificate of Registration No	
10.4 Validity period	

10.5 Any other NMRA documents/ reference No (if available)	

Declaration of the applicant

I, …… the undersigned, hereby declare that all the information submitted with this application is true and correct and certify that all documents uploaded in support of this application are accurate and most recent as per to date.

Signature :

Date :

Document required for Waiver of Registration (If available please tick "√")

Note : The NMRA may be required more data where necessary.

1.	Letter of Authorization from the manufacturer	☐
2.	Agency transfer letter issued by NMRA	☐
3.	Sample import licence issued by NMRA	☐
4.	Certificate of Registration issued by NMRA	☐
4.	Free sale Certificate issued by Health Authority of Country of Origin of the Product	☐
5.	ISO certificate for quality management system	☐
6.	CE self declaration by manufacturer/ EC certificate for full Quality Assursnce system	☐
7.	Labels of the product	☐
8.	Product Information Leaflet / Catalogs	☐
9.	Report of Technical Evaluation Committee (TEC)	☐
10.	Approval of Procurement Committee	☐
11.	Purchase order / Indent/Commercial invoice	☐
12.	Registration of Medical Council – Sri Lanka	☐
13.	Ethic review committee approval (Applicable for research items)	☐

14.	Research proposal (Applicable for research items)	
15.	No Objection Letter (NOL) from local agent	☐
16.	Sri Lanka Custom Detained Document	☐
17.	Recommendation of Professional bodies (Colleges/Institutions)	☐
18	Request of Professional bodies (Colleges/Institutions)	