



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

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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	
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3. 2 Name of physical manufacturer & country (If applicable)	
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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	<input type="checkbox"/>
8.2 Registered sources not quoted	<input type="checkbox"/>

- | | |
|---|--------------------------|
| 8.3 Lowest price than registered item | <input type="checkbox"/> |
| 8.4 Registered product not complied with tender specification | <input type="checkbox"/> |
| 8.5 Manufacturer's name changed | <input type="checkbox"/> |
| 8.6 Government to Government agreement | <input type="checkbox"/> |
| 8.7 No registered sources | <input type="checkbox"/> |
| 8.8 Short shelf life of the product | <input type="checkbox"/> |
| 8.9 Research | <input type="checkbox"/> |
| 8.10 Donation | |
| 8.11 Other (If so reason should be mentioned) | <input type="checkbox"/> |

Remarks

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9. Sample evaluation detail (if applicable)

9.1 Name 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)	
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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 “v”)

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

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

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