[Applicant Letterhead]
(Include logo, full address, contact number, email, and website)

Date:

Chief Executive Officer,
National Medicines Regulatory Authority (NMRA)
Sri Lanka

Declaration Letter Confirming the Type of Medical Device Dossier Submitted

Dear Sir/Madam,

We, **[Applicant Company Name]**, duly appointed as the authorized local agent for **[Manufacturer's Name]**, located at **[Manufacturer's Address]**, hereby confirm that the following medical device is being submitted to your esteemed Authority with the specified type of regulatory dossier:

Generic Name of the Medical Device:
Brand Name:
Manufacturer Name:
Manufacturer Address:
Local Agent Name:
Type of Consolidated Dossier Submitted:

- ☐ FMSA +PRD application/ non-reliance
- ☐ FMSA +PRD application/reliance
- ☐ PRD application/ non- reliance
- ☐ PRD application/ reliance
- ☐ Locally Manufactured

We confirm that the submitted dossier type complies with the applicable regulatory requirements of the NMRA and includes all necessary supporting documents.

Should any further clarification or supporting information be required, we are committed to providing prompt assistance.

Thank you for your kind consideration.

Sincerely,

…….
Name of the signatory:
Designation:
Company seal: