1.0 PURPOSE

The purpose of this procedure is to describe the import registration process of medical device.

2.0 SCOPE

This procedure is applicable for the RA services we provide to foreign medical device manufacturers.

3.0 RESPONSIBILITY

RA Associates, Executive-RA, DRA Consultant, Sr. Consultant, Chief Consultant & Proprietor

4.0 PROCEDURE

i. **Step 1:** Primary approval by DGDA
   Collect all the required documents as pdf scanned copy from the manufacturer. No original documents required in step 1.
   List of required documents can be found in https://pharmadra.net/pages/required-documents/
ii. Complete the gap-analysis for primary application submission withing 3 working days.
iii. Deposit the Govt. fees for primary application upon the receipt of fund from the manufacturer.
iv. Submit the primary application along with all required documents and Govt. fees.
v. DGDA (Directorate General of Drug administration) fix an evaluation meeting date, usually every 2-3 months. Application will be approved or rejected.
vi. If approved, start step 2, if rejected, submit again to the next evaluation meeting.
vii. **Step 2:** Final approval by DGDA
   After receiving the primary approval letter from DGDA, collect the original FSC/CFG, original product label/empty box from the manufacturer.
viii. Deposit the Govt. fees. Attach the original TR Chalan copies with the application.
ix. Submit the application to DGDA and follow-up 3-5 days a week. Try to get the final registration approval within 30 working days.
x. After receiving original registration certificate & approval letter from DGDA, share the pdf versions with the manufacturer (i.e. representative of the manufacture)

Prepared by:	*Checked by:*	*Approved by:*	
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