REQUIREMENTS FOR MEDICAL DEVICE DISTRIBUTION PERMIT NOTIFICATION		
Requirement		**Description**
1	HS Code Product	
2.3	Copy of POA (Power of Attorney) / LOA (Letter of Authorization) as sole agent or sole distributor/ distributor who has authorization from principle/ manufacturer to register the medical device at Ministry of Health which legalized by KBRI (ID embassy in country of principle/ manufacturer). POA needs to listed product codes.	A LOA with a minimum validity of 2 years and Apostille certification is required. The distribution license validity will align with the LOA duration, up to a maximum of 5 years. For OEM products, the maximum validity is 3 years.
2.4	Give the Certificate of Free Sale from authorized institutions	FSC/ Certificate of Exportation of Medical Products
2.5	Original copy / scan license and documents verifying conformity to product standards, terms of safety, effectiveness and quality systems in the design and manufacturing process (ISO 9001, ISO 13485, CE CERTIFICATE)	ISO 13485 is a must
2.6	The standards used and proof of compliance against the standard	For imported medical devices provide the Declaration of Conformity of the factory (DoC) along with a list of standards used and an explanation.
2.7	Brand Registration	Brand registration or trademark certificate issued by any country
3.1	Material	- Name of Raw Materials - Formula Qualitative and Quantitative
3.2	Provide the functional characteristics and technical performance specifications tool	Usually in the form of a brochure
3.3	Give an example of labeling	1. Please attach a photo of the finished product. 2. Please attach the label design. 3. Please attach the packaging design. 4. Please indicate the label placement on the packaging.
3.4	Give and explain user manuals, training materials and instructions for installation and maintenance	Instruction For Use
3.5	List of Accessories / Code / Type / Size	A product list containing the name, type/code, specifications, along with images and functions of the type/accessories.
3.6	COA, QC Pass / Inspection Report	
3.7	Production Process	in the form of a flowchart