MEDICAL DEVICE DISTRIBUTION LICENSE REQUIREMENTS (AKL) *Risk Class 1A*		
Requirement		**Description**
1	HS Code Product	
Form A (Administration Data)		
A.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.
A.4	Give the Certificate of Free Sale from authorized institutions	FSC/ Certificate of Exportation of Medical Products
A.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
A.6	Give exclusive summary (Executive Summary) / Summary of Product : - Executive Summary Product (short) - Marketing History / History of Use - The intended use - Formula / Components - History of Use - Work mechanism	Executive summary and history of product usage in any marketed country, accompanied by proof such as a Certificate of Free Sale (CFS) or market approval, including screenshots, website URLs, and marketing authorization or permit documents
A.7	The standards used and proof of compliance against the standard	Provide the Declaration of Conformity of the factory (DoC) along with a list of standards used and an explanation.
A.8	Brand Registration	Brand registration or trademark certificate issued by any country
Form B (Product Information)		
B. 1-10	1. Description Product 2. Description and features of Medical Devices 3. The intended use 4. Indication 5. Instruction For Use 6. Contraindication 7. Warning 8. Attention 9. Unwanted Potential Effects 10. Alternative Therapies	If available
B.11	Material	- Name of Raw Materials - Formula Qualitative and Quantitative

B.13	Production Process	Production process in the form of a flowchart
Form C (Specification and Quality Assurance)		
C.1	Describe the functional characteristics and technical performance specifications tool	Product's functions and specs.
C.2	Provide additional information tool characteristics that have not been included in the previous section	Brochure/Catalogue
C.3	Provide a summary of the verification plan and document validation	For Sterile Product : Please attach the complete sterilization validation protocol from the factory, mark the name of the product and the results of the sterilization. If the sterilization process is carried out by a third party, also attach the ISO of the sterilization facility.
C.4	Pre-clinical studies	If available
C.10	Give the specifications and or raw material requirements	If available
C.13	Provide analysis of test results or the results of clinical trials and the safety of medical devices (IEC, COA, QC Pass / Inspection Report)	Certificate of Analysis, QC Pass, or Inspection Report detailing finished product testing, including testing methods, standards applied, and test results. For quantitative tests, provide actual numerical values rather than just "PASS" or "compliant." Additionally, include the name and signature of the approver or QC personnel as evidence of approval.
Form D (Labeling)		
D.1	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.
D.3	Give and explain user manuals, training materials and instructions for installation and maintenance	Instruction For Use
D.4	Give the production code and meaning	In document format
D.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.

PERSYARATAN IZIN EDAR (AKD)

	Persyaratan	Keterangan
1	**Formulir Pendaftaran**	Format Sudah ada tinggal mengikuti
2	**Form A**	
2.1	Sertifikat Produksi/ Sertifikat Standard	Milik Pabrikan
2.2	IPAK	Milik Distributor
2.3	Foto copy surat kuasa sebagai sole agent atau sole distributor/distributor yang diberi kuasa mendaftar alat kesehatan ke Kementerian Kesehatan dari prinsipal / pabrik asal yang telah dilegalisir KBRI	tidak diperlukan karena AKD
2.4	Certificate of Free Sale dari lembaga yang berwenang	tidak diperlukan karena AKD
2.5	Sertifikat ISO 9001/13485/CE milik Pabrik/CPAKB	Wajib memiliki sertifikat CPAKB sudah memiliki sertifikat CPAKB
2.6	Ringkasan eksklusif (Executive Summary) / Ringkasan Produk (tujuan penggunaan, deskripsi produk dan komponen atau formula secara singkat dan jelas)	Executive Summary dikeluarkan oleh pabrikan
2.7	Declaration of Conformity (Surat Pernyataan Kesesuaian Standard) dari pabrik, surat yg menyatakan bahwa produk alkes tsb sudah mengikuti aturan yang berlaku sesuai standar alat kesehatan	Dikeluarkan oleh pabrikan
2.8	Surat pernyataan Paten Merk / Surat Pelepasan Keagenan	Dibuat oleh distributor/ Pemegang Merk
2.9	Surat pernyataan keaslian data dokumen /data yang diupload	Dibuat oleh distributor/ Pemegang Merk
2.10	Surat Pakta Integritas	Dibuat oleh distributor/ Pemegang Merk
3	**Form B**	
3.1	Uraian Alat	Fitur sesuai dengan produk
3.2	Deskripsi dan Fitur Alat	Fitur sesuai dengan produk
3.3	Tujuan Penggunaan	Bisa dibantu dicarikan
3.4	Indikasi	
3.5	Petunjuk penggunaan	
3.6	Kontraindikasi	
3.7	Peringatan (bila ada)	
3.8	Perhatian (bila ada)	
3.9	Potensi Efek Yang Tidak Diinginkan	
3.10	Alternatif Terapi	
3.11	Material Bahan Baku	- List formula - Invoice pembelian bahan baku
3.12	Informasi Pabrik	
3.13	Proses Produksi	Video proses produksi dan QC
4	**Form C**	
4.1	Karakteristik fungsional dan Spesifikasi kinerja teknis alat	Sesuai dengan spesifikasi alat
4.2	Informasi tambahan karakteristik alat yang belum dicantumkan pada bagian sebelumnya	Bila ada
4.3	Ringkasan dari verifikasi rancangan dan dokumen validasi	Harus ada bila produk merupakan produk Steril
4.4	Studi Pre-klinis	Bila ada
4.5	hasil pengujian validasi piranti lunak (jika dapat diterapkan)	
4.6	Hasil penelitian untuk alat yang mengandung material biologi	
4.7	Bukti Klinis	
4.8	Jelaskan analisa resiko dari alat	
4.9	Berikan hasil analisa resiko (wajib untuk kelas III)	
4.10	Berikan spesifikasi dan atau persyaratan bahan baku	

PERSYARATAN IZIN EDAR (AKD)

	Persyaratan	Keterangan
4.11	Berikan spesifikasi kemasan (produk diagnostic)	
4.12	Berikan data hasil analisis dan atau uji klinis (spesifitas, sensitivitas dan stabilitas) untuk pereaksi atau produk diagnostic in vitro	
4.13	Berikan hasil uji analisis atau hasil uji klinis dan keamanan alat kesehatan (IEC, COA, QC Pass / Inspection Report, BAPETEN - Wajib untuk Kelas 2 dan Kelas 3)	Dikeluarkan oleh pabrikan
5	Form D	
5.1	Contoh Penandaan	Lampirkan Desain Penandaan
5.2	Penjelasan penandaan pada alat	
5.3	Penjelasan petunjuk penggunaan, materi pelatihan & petunjuk pemasangan serta pemeliharaan	Petunjuk penggunaan dalam bahasa inggris dan bahasa indonesia
5.4	Lampirkan kode produksi dan artinya	
5.5	Daftar Aksesoris / Kode / Type / Ukuran	dibuat dalam bentuk excel untuk aksesoris produk tsb bila ada
5.6	Data Pendukung Lampiran Aksesoris	berisi nama dan fungsi aksesoris tsb
6	Form E	
6.1	Melampirkan prosedur yang digunakan dan sistem pencatatan, penanganan komplain, Laporan Kejadian Efek yang tidak diinginkan dan Prosedur Recall	Bisa dibantu dibuatkan