



Naramedic.

Regulatory Affairs & Market Access
Specialist For Medical Devices

SYARAT PRODUK PKRT DALAM NEGERI (PKD)

No	Item	Ket
1	Berbadan Hukum Minimal CV atau PT, *TIDAK DIPERBOLEHKAN PT PERSEORANGAN	KBLI 20231
2	KTP Direktur	
3	Nama / KTP PJT	
4	Kop Surat Perusahaan	
5	Username & Password OSS	
6	Bukti Tanda Daftar Merk / Sertifikat Merek	
7	Desain Kemasan Produk	
8	Spesifikasi dan Ukuran Kemasan Produk	
9	Formula Produk	
10	COA Bahan Baku Produk	
11	Hasil Uji Lab (Jika diperlukan)	



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ALUR PROSES PERIZINAN PKRT (IMPORT/PKL)

Memiliki
Badan Usaha
Min. Berupa
PT

• KBLI 46499



Melengkapi
Persyaratan
Izin Edar PKRT
Import

• Terlampir

No.	Requirements	Description
1	Original copy / scan of the power of attorney / LOA as sole agent or sole distributor who is authorized to register the product PKRT to the Ministry of Health of the principal / plant origin that have legalized the Embassy (Import)	Min. LoA 2 years
2	[The certificate has been circulating in the country of origin for imported products (Certificate of Free Sale / CFS)	
3	Certificate of ISO, GMP factory (import), min ISO 9001 / ISO 22716	
4	Formula (qualitative and quantitative) and the function of each ingredient used - Total Formula must be 100%	
5	Production Process	
6	Describe the specifications of each of the raw materials	
7	Certificates of laboratory tests and materials used	
8	Specification of container and lid	
9	Specifications and inspection procedures finished products (COA)	
10	Finished product stability report and limit expired if there is	
11	Example of a production code and explain the meaning	
12	Labeling Design	

