



TÜRKİYE CUMHURİYETİ
TİCARET BAKANLIĞI

MALEZYA
KUALA LUMPUR
TİCARET MÜŞAVİRLİĞİ

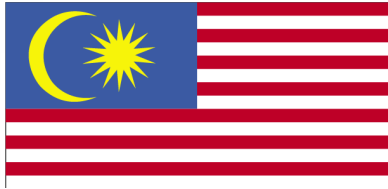
Münevver Koçak
Ticaret Müşaviri

Merve Kadiroğlu
Ticaret Müşaviri

7 Temmuz 2023



T.C. TİCARET
BAKANLIĞI



MALEZYA





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BAKANLIĞI

MALEZYA



RESMİ ADI	Malezya
BAŞKENTİ	Kuala Lumpur (İdari Başkenti: Putrajaya)
BAĞIMSIZLIK TARİHİ	31 Ağustos 1957
YÖNETİM BİÇİMİ	Federatif Anayasal Monarşi
DEVLET BAŞKANI	Sultan Abdullah Sultan Ahmad Shah (24 Ocak 2019'dan beri)
BAŞBAKAN	Anwar Ibrahim (24 Kasım 2022'den beri)
İDARİ YAPI	13 eyalet ve 3 federal bölge Eyaletler: Johor, Kedah, Kelantan, Malacca, Negeri Sembilan, Pahang, Perak, Perlis, Penang, Selangor, Terengganu, Sabah ve Sarawak Federal Bölgeler: Kuala Lumpur, Labuan, Putrajaya
RESMİ DİL	Malayca (Resmi dil) İngilizce (ikincil dil olarak tanımlanmakta ve yaygın olarak kullanılmaktadır), Çince (Mandarin, Kanton, Hakka), Tamil ve Doğu Malezya'da konuşulan diğer yerel diller de kullanılmaktadır.
ETNİK YAPI	Malay (Bumiputra) %69,3, Çinli %22,8, Hintli %6,9, Diğer (%1)



Genel Ekonomik Göstergeler

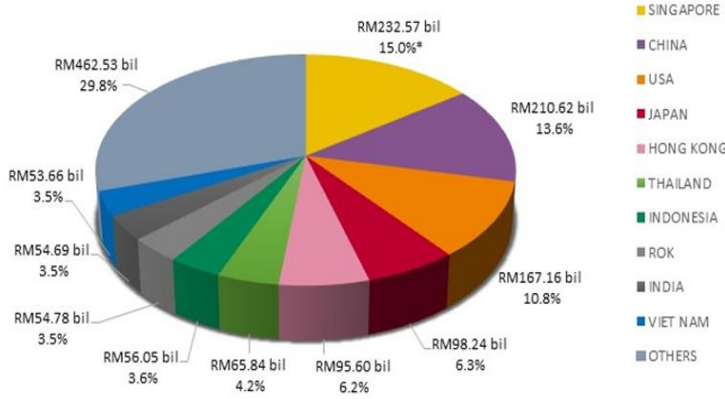
	2019	2020	2021	2022
Nüfus (Milyon)	31,9	32,6	32,7	33,5
GSYH, Milyar (ABD Doları) - GDP	364	337	365	370
GSYH Artış Hızı (%) GDP Growth Rate (%)	4,3	-5,6	3,1	8,7
Kişi Başına GSYH (ABD Doları)	11.414	10.401	10.897	12.001
Enflasyon (Tüfe), (Yıllık Ortalama Artış %)	0,7	-1,1	2,4	3,3
İşsizlik Oranı (%)	3,3	4,5	4,6	3,8
Döviz Kuru (USD/RM, Yıllık Ortalama)	4,14	4,2	4,14	4,14
Mal İhracatı, (Milyar ABD Doları)	238,2	234,1	299,0	353
Mal İthalatı, (Milyar ABD Doları)	205	189,9	238,1	294

Kaynak: IMF, Dünya Bankası, DTÖ, Malezya İstatistik Kurumu, Economic Planning Unit Malaysia



MALEZYA'NIN İHRACATINDA BAŞLICA TİCARET ORTAKLARI ve TÜRKİYE

Top 10 Major Export Countries, 2022
Total Exports: RM1.552 trillion



MALEZYA'NIN İHRACATINDAKİ İLK 10 ÜLKE VE TÜRKİYE (1000 \$)										
		2015	2016	2017	2018	2019	2020	2021	2022	
	Dünya	200,890,906	189,863,395	217,715,510	247,489,373	238,161,125	233,553,703	299,230,239	352,331,133	
1	Singapur	27,937,522	27,646,509	31,558,974	34,498,254	33,050,887	33,846,404	41,847,444	52,842,667	
2	Çin	26,151,439	23,809,577	29,361,911	34,439,740	33,706,910	37,758,818	46,351,698	47,857,101	
3	ABD	18,992,742	19,399,587	20,662,227	22,546,148	23,146,016	25,940,693	34,329,392	37,981,792	
4	Japonya	19,011,633	15,286,460	17,431,058	17,125,944	15,753,503	14,686,769	18,166,710	22,321,773	
5	Hong Kong	9,491,951	9,093,297	11,105,367	18,497,482	16,066,857	16,219,177	18,494,029	21,721,048	
6	Tayland	11,442,103	10,653,435	11,759,167	14,076,943	13,475,084	10,777,697	12,646,123	14,960,824	
7	Endonezya	7,452,096	6,736,577	7,820,405	7,907,124	7,562,571	7,039,080	9,465,137	12,736,125	
8	Hindistan	6,498,216	7,731,846	8,042,800	9,000,166	9,065,941	7,234,657	10,905,258	12,425,818	
9	Vietnam	4,480,825	5,743,851	6,426,396	8,483,356	8,385,130	7,353,965	10,982,091	12,191,517	
10	Tayvan	6,118,015	5,116,198	5,501,292	8,065,739	8,920,160	8,060,211	9,784,217	11,745,721	
24	Türkiye	978,509	1,732,911	2,446,265	1,975,535	1,682,257	1,815,283	3,409,108	3,951,171	

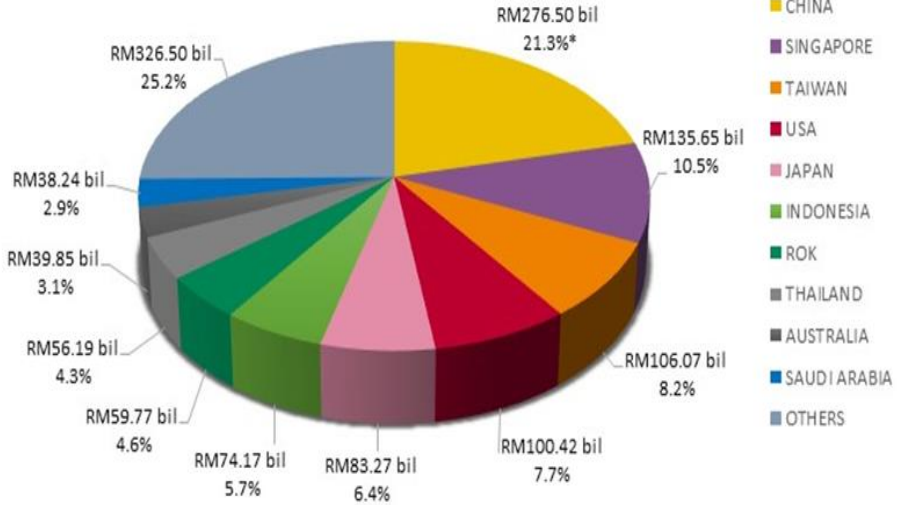
Kaynak: Matrade, Department of Statistics Malaysia

*Sıralama 2022 yılına göre yapılmıştır.



MALEZYA'NIN İTHALATINDA BAŞLICA TİCARET ORTAKLARI ve TÜRKİYE

Top 10 Major Import Countries, 2022
Total Imports: RM1.297 trillion



MALEZYA'NIN İTHALATINDAKİ İLK 10 ÜLKE VE TÜRKİYE (1000 \$)		2015	2016	2017	2018	2019	2020	2021	2022
	Dünya	175,592,994	168,459,048	194,498,694	218,032,319	205,047,872	190,432,097	238,298,934	294,287,187
1	Çin	33,102,114	34,324,253	38,239,395	43,471,586	42,405,983	40,722,458	58,639,339	62,826,268
2	Singapur	21,046,074	17,452,394	21,562,883	25,542,992	21,604,390	17,520,925	23,974,674	30,821,655
3	Tayvan	9,396,681	10,079,836	12,732,440	15,755,393	13,770,818	13,716,220	19,255,752	24,100,563
4	ABD	14,170,709	13,417,057	15,178,721	16,095,199	16,578,914	16,501,202	19,133,807	22,818,126
5	Japonya	13,720,147	13,736,220	14,791,813	15,825,117	15,351,674	14,521,042	18,932,870	18,920,488
6	Endonezya	7,937,475	7,108,070	8,808,351	10,034,263	9,389,979	8,701,670	14,371,223	16,853,434
7	Kore	8,000,261	8,840,906	9,096,564	9,735,301	9,373,125	10,756,429	12,823,887	13,581,362
8	Tayland	10,667,032	10,203,748	11,194,591	12,049,890	10,688,369	8,123,712	11,620,321	12,766,467
9	Avustralya	4,505,234	3,763,033	4,672,080	5,349,065	5,629,949	4,632,027	2,554,032	9,053,773
10	Suudi Arabistan	1,926,814	2,567,501	2,485,624	4,436,292	4,540,215	3,839,705	3,201,299	8,688,537
36	Türkiye	463,335	300,121	360,758	452,878	428,132	474,952	728,441	649,570

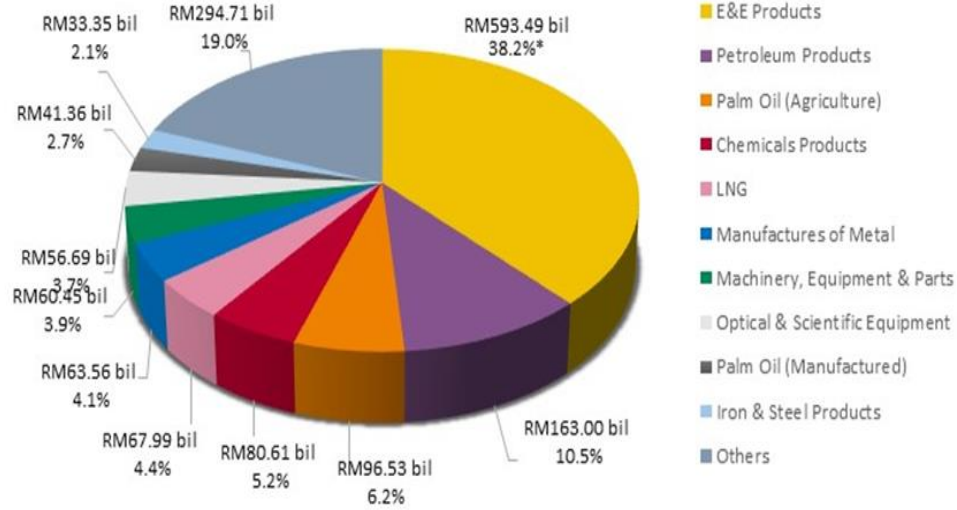
Kaynak: Matrade, Department of Statistics Malaysia

*Sıralama 2022 yılına göre yapılmıştır.



MALEZYA'NIN İHRACATINDA İLK 10 ÜRÜN (1000 \$)

Top 10 Major Export Products, 2022
Total Exports: RM1.552 trillion



- %38,2 elektrik ve elektronik ürünler
- %10,5 petrol ürünleri
- %6,2 palm yağı ve türevleri
- %5,2 kimyasallar
- %4,4 LNG

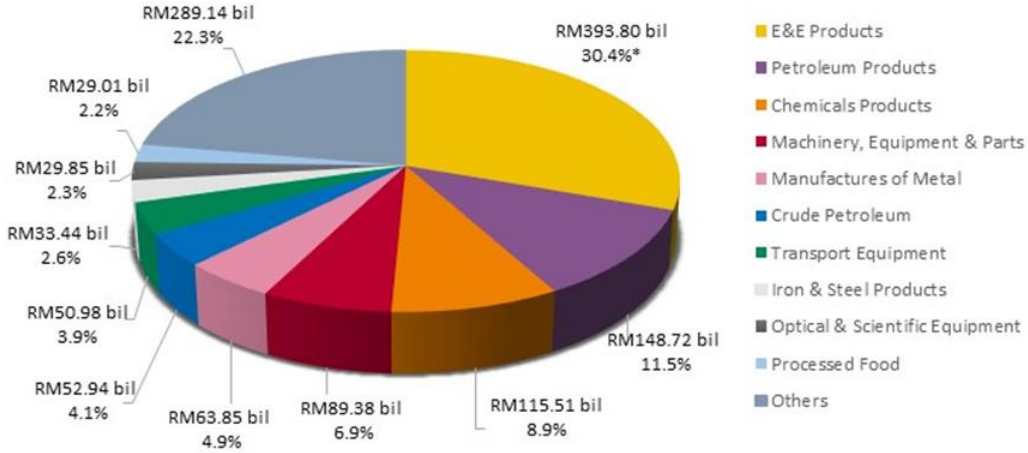
Malezya'nın Dünyaya İhracatında İlk 10 Ürün (Milyon \$)				
GTİP Kodu	GTİP Adı (Türkçe)	2021	2022	2022/2021 Değişim (%)
		2021 (Ocak-Aralık)	2022 (Ocak-Aralık)	
854231	ELEKTRONİK ENTEGRE DEVRELER; İŞLEMCİ VE KONTROLÖR	31.173,71	37.135,96	19,13
271019	DİĞER YAĞLAR VE MÜSTAHAZARLAR	13.443,13	23.765,34	76,78
854239	DİĞER ENTEGRE DEVRELERİ	15.518,92	19.980,00	28,75
271111	DOĞAL GAZ - SIVILAŞTIRILMIŞ	8.830,99	15.447,39	74,92
151190	PALM YAĞI VE FRAKSİYONLARI; DİĞER	9.255,94	12.487,28	34,91
271012	HAFIF YAĞLAR VE MÜSTAHAZARLARI; ESAS UNSUR OLARAK, AĞIRLIK İTIBARIYLA % 70 VEYA DAHA FAZLA PETROL YAĞLARI VEYA BITÜMENLİ MINERALLERDEN ELDE EDİLEN YAĞLARI İÇERENLER (BIODİZEL İHTİVA EDENLER VE ATIK YAĞLAR HARIÇ)	7.351,63	10.673,89	45,19
854290	ELEKTRONİK ENTEGRE DEVRELERİN AKSAM VE PARÇALARI	4.782,43	9.901,75	107,04
854232	BELLEKLER	5.712,67	8.917,52	56,10
270900	PETROL YAĞLARI VE BITÜMENLİ MINERALLERDEN ELDE EDİLEN YAĞLARIN(HAM) DİĞERLERİ	5.235,44	7.930,57	51,48
851762	SES, GÖRÜNTÜ VEYA DİĞER BİLGİLERİ ALMAYA,ÇEVİRMEME VE VERMEYE VEYA YENİDEN OLUŞTURMAYA MAHSUS MAKİNALAR	4.897,81	6.776,89	38,37

Kaynak: Matrade, Department of Statistics Malaysia



MALEZYA'NIN İTHALATINDA İLK 10 ÜRÜN (1000 \$)

Top 10 Major Import Products, 2022
Total Imports: RM1.297 trillion



%30,4 elektrik ve elektronik ürünler
%11,5 ham petrol ve petrol ürünleri
%8,9 kimyasallar
%6,9 makine ve ekipmanlar
%4,9 metal ve türevleri

Malezya'nın Dünyadan İthalatında İlk 10 Ürün (Milyon \$)				
GTİP Kodu	GTİP Adı (Türkçe)	2021	2022	2021/2020 Değişim (%)
		Yıllık	Yıllık	
854231	ELEKTRONİK ENTEGRE DEVRELER; İŞLEMCİ VE KONTROLÖR	17.679,88	21.265,98	20,28
271019	DİĞER YAĞLAR VE MÜSTAHZARLAR	10.507,32	17.032,78	62,10
271012	HAFIF YAĞLAR VE MÜSTAHZARLARI; ESAS UNSUR OLARAK, AĞIRLIK İTİBARIYLA % 70 VEYA DAHA FAZLA PETROL YAĞLARI VEYA BITÜMENLİ MINERALLERDEN ELDE EDİLEN YAĞLARI İÇERENLER (BİODİZEL İHTİVA EDENLER VE ATIK YAĞLAR HARIÇ)	9.523,17	14.738,12	54,76
270900	PETROL YAĞLARI VE BITÜMENLİ MINERALLERDEN ELDE EDİLEN YAĞLARIN(HAM) DİĞERLERİ	3.477,51	12.220,44	251,41
854290	ELEKTRONİK ENTEGRE DEVRELERİN AKSAM VE PARÇALARI	9.393,79	11.344,43	20,77
854239	DİĞER ENTEGRE DEVRELERİ	9.008,24	10.766,27	19,52
854232	BELLEKLER	6.442,23	9.882,46	53,40
270119	DİĞER TAŞKÖMÜRLERİ	3.539,38	5.979,65	68,95
853400	BASKI DEVRELER	3.098,73	3.689,68	19,07
740311	RAFİNE EDİLMİŞ BAKIR KATOTLAR VE KATOT PARÇALARI	2.250,89	2.506,91	11,37

Kaynak: Matrade, Department of Statistics Malaysia



Türkiye-Malezya İkili Ticari İlişkileri

İKİLİ TİCARET VERİLERİ (1.000 Dolar)

Yıl	İhracat \$ / Bin	İhracat Değişim %	İthalat \$ / Bin	İthalat Değişim %	Hacim \$ / Bin	Denge \$ / Bin
2016	321.564	-9,9	1.996.955	49,1	2.318.519	-1.675.392
2017	286.255	-11,0	3.138.558	57,2	3.424.814	-2.852.303
2018	365.403	27,6	2.132.975	-32,0	2.498.378	-1.767.573
2019	354.238	-3,1	1.847.831	-13,4	2.202.069	-1.493.592
2020	381.913	7,8	1.989.963	7,7	2.371.876	-1.608.051
2021	445.166	16,6	3.098.059	55,7	3.543.225	-2.652.894
2022	478.255	7,4	4.288.701	38,4	4.766.955	-3.810.446

Malezya'dan ithalatımızın sadece %9,8'i tüketim mallarından, geriye kalan %90,2'si ara ve yatırım mallarından oluşmaktadır.

Türkiye'nin 2022 yılında, Malezya'ya ihracatı, bir önceki yıla kıyasla %7,4 artarak 478 milyon dolar olarak gerçekleşmiştir.

2022 yılında Malezya'dan ithalatımız ise bir önceki yıla göre %38,4 artarak yaklaşık 4.3 milyar dolara ulaşmıştır.

Türkiye'nin Malezya'ya İhracatında Başlıca Ürünler



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BAKANLIĞI

SITC Kodu	SITC Adı	2022 (1-12)				
		2021(\$)	2022 (\$)	Değişim (%)	Ülke Payı (%)	Genel Payı (%)
89	Tanklar ve diğer zırhlı savaş taşıtları (motorlu) (silahla donatılmış olsun/olmasın)	54.712.921	81.588.543	49,12	17,06	0,03
8973	Altın, gümüş, platin gibi kıymetli metallere mücevher	49.205.185	66.953.469	36,07	14,00	0,03
8911	Harp silahları, tanklar, revolver, tabanca, kesici, dürtücü silahlar	1.990.807	11.457.096	475,50	2,40	0,00
8931	Eşya taşıma ambalajı için plastik mamulleri, tıpa, kapak, kapsül	944.609	754.148	-20,16	0,16	0,00
65	Tekstil ürünleri (iplik, kumaş, yer kaplamaları, hazır eşya)	31.781.068	48.660.423	53,11	10,17	0,02
6595	Dokunmuş halılar ve dokumaya elverişli maddelerden yer kaplamaları.	25.750.379	41.781.796	62,26	8,74	0,02
6531	Sentetik iplik, monofil, şeritlerle dokumalar	1.044.440	1.609.459	54,10	0,34	0,00
52	İnorganik kimyasal ürünler	26.462.594	37.154.809	40,41	7,77	0,01
5237	Karbonatlar, peroksikarbonatlar, amonyum karbonat	13.122.310	18.387.769	40,13	3,84	0,01
5238	Diğer metal tuzları ve İnorganik asitlerin peroxy tuzları	8.132.412	12.850.189	58,01	2,69	0,01
67	Demir ve çelik	92.200.540	36.288.789	-60,64	7,59	0,01
6768	Demir veya çelikten profiller	70.020.950	26.007.587	-62,86	5,44	0,01
6762	Demir-çelik çubuklar (sıcak işlenmiş)	19.865.493	6.758.092	-65,98	1,41	0,00
28	Metal cevherleri, döküntüleri, hurdaları	14.837.331	24.729.412	66,67	5,17	0,01
2831	Bakır cevherleri ve konsantreleri	13.456.198	9.800.792	-27,17	2,05	0,00
2891	Kıymetli metal cevherleri-konsantreleri		14.192.373		2,97	0,01
05	Meyve ve sebzeler	25.844.472	23.070.704	-10,73	4,82	0,01
0567	Sebze, meyva, bitki ve yemiş konserveleri	4.468.312	5.214.581	16,70	1,09	0,00
0574	Elma (taze)	5.916.425	4.172.194	-29,48	0,87	0,00
84	Giyim eşyası ve bunların aksesuarları	15.758.036	21.397.980	35,79	4,47	0,01
8454	Tişörtler, fanilalar, diğer iç giyim eşyası-örülmüş	3.165.662	4.096.313	29,40	0,86	0,00
8424	Kadın/kız çocuklar için elbiseler	1.482.465	2.243.213	51,32	0,47	0,00
27	Hayvansal ve bitkisel gübreler, tuz, kükürt, toprak, alçı gibi mineral maddeler	11.861.330	21.073.059	77,66	4,41	0,01
2789	Tebeşir, barit, borat, silisli fosil unu, asfalt ve başka yerde belirtilmeyen mineraller	8.500.800	17.747.330	108,77	3,71	0,01
2785	Kuvars, kuvarzit, mika, feldispat, florspat vs.	2.368.338	2.406.029	1,59	0,50	0,00
77	Elektrik makinaları, cihazları ve aletleri, vb. aksam, parçaları	14.620.427	17.289.576	18,26	3,62	0,01
7711	Elektrikli transformatörler	3.935.748	4.873.240	23,82	1,02	0,00
7751	Çamaşır ve kurutma makinaları: kapasitesi=<10 kg	1.531.789	2.911.100	90,05	0,61	0,00
97	Altın, parasal olmayan (altın cevheri ve konsantrasyonu hariç)	15.931.647	16.290.483	2,25	3,41	0,01
9710	Altın, parasal olmayan (altın cevheri ve konsantrasyonu hariç)	15.931.647	16.290.483	2,25	3,41	0,01
	İLK 10 TOPLAM	307.621.786	334.854.465			
	ÜLKE TOPLAM	445.165.759	478.254.574	7,43		0,19
	GENEL TOPLAM	225.214.458.038	254.171.899.466	12,86		

Türkiye'nin Malezya'dan İthalatında Başlıca Ürünler



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SITC Kodu	SITC Adı	2022 (1-12)				
		2021 (\$)	2022 (\$)	Değişim (%)	Ülke Payı (%)	Genel Payı (%)
68	Demir ihtiva etmeyen madenler	547.776.227	1.025.135.696	87,14	23,90	0,28
6841	İşlenmemiş alüminyum	511.004.045	936.417.421	83,25	21,83	0,26
6842	İşlenmiş alüminyum	7.554.353	52.257.760	591,76	1,22	0,01
42	Bitkisel sıvı yağlar ve fraksiyonları (rafine edilmiş olsun olmasın, kimyasal işlem görmemiş)	729.828.073	995.898.948	36,46	23,22	0,27
4222	Palm yağı ve fraksiyonları	602.192.525	833.852.086	38,47	19,44	0,23
4224	Palm çekirdeği-babassu yağları ve fraksiyonları	102.742.352	121.957.889	18,70	2,84	0,03
77	Elektrik makinaları, cihazları ve aletleri, vb. aksam, parçaları	273.876.402	545.820.613	99,29	12,73	0,15
7763	Diyotlar, transistörler vb. yarı iletken tertibat	38.193.718	245.478.649	542,72	5,72	0,07
7764	Elektronik devreler	48.895.883	70.218.310	43,61	1,64	0,02
65	Tekstil ürünleri (iplik, kumaş, yer kaplamaları, hazır eşya)	153.274.274	226.508.307	47,78	5,28	0,06
6516	Sentetik filament iplikler	68.086.055	93.845.891	37,83	2,19	0,03
6531	Sentetik iplik, monofil, şeritlerle dokumalar	48.898.171	80.869.111	65,38	1,89	0,02
51	Organik kimyasal ürünler	181.664.277	189.016.423	4,05	4,41	0,05
5121	Asiklik monohidrik alkoller	119.311.011	127.921.687	7,22	2,98	0,04
5138	Polikarboksilik asitler, anhidritleri, halojenürleri türevleri	43.224.615	26.373.321	-38,99	0,61	0,01
84	Giyim eşyası ve bunların aksesuarları	316.849.936	171.040.121	-46,02	3,99	0,05
8482	Vulkanize kauçuktan/plastikten; eldiven, giyim eşyası ve aksesuarı	289.802.363	134.253.740	-53,67	3,13	0,04
8423	Kadın/kız çocuklar için ceket, blazer	2.704.819	7.405.304	173,78	0,17	0,00
66	Taş, alçı, çimento, amiyant, cam, seramik vb. maddeden eşya	59.064.130	134.004.748	126,88	3,12	0,04
6647	Emniyet camları	56.513.036	130.059.022	130,14	3,03	0,04
6661	Porselenden ve seramikten ev eşyası, tuvalet eşyası	1.536.764	1.593.371	3,68	0,04	0,00
57	İlk şekillerde plastikler	109.203.174	101.354.013	-7,19	2,36	0,03
5743	Polikarbonatlar, alkid reçineler ve diğer polysterler (ilk şekillerde)	75.198.205	61.495.773	-18,22	1,43	0,02
5729	Diğer stiren polimerleri	6.718.621	15.169.836	125,79	0,35	0,00
55	Uçucu yağlar, parfüm, kozmetik, tuvalet müstahzarları	63.467.234	86.398.297	36,13	2,01	0,02
5541	Sabunlar, yüzey aktif organik maddeler	51.360.130	76.378.420	48,71	1,78	0,02
5542	Yıkama, temizleme müstahzarları-sabunlar hariç	9.427.280	7.593.118	-19,46	0,18	0,00
26	Dokuma elyafı ve bunların artıkları	69.034.585	81.947.894	18,71	1,91	0,02
2665	Sentetik devamsız lifler (işlem görmemiş)	68.713.637	81.862.047	19,14	1,91	0,02
	İLK 10 TOPLAM	2.475.661.457	3.531.332.779			
	ÜLKE TOPLAM	2.999.859.499	4.099.798.654	33,68	1,19	0,04



T.C. TİCARET
BAKANLIĞI

İkili Serbest Ticaret Anlaşmaları

Türkiye, Japonya, Pakistan, Hindistan,
Yeni Zelanda, Şili, Avustralya

Bölgesel STA'ları



ASEAN (ATIGA)

ASEAN-Çin
ASEAN-Avustralya-Yeni Zelanda
ASEAN-Güney Kore
ASEAN-Japonya
ASEAN-Hindistan

Bölgesel Kapsamlı Ekonomik Ortaklık-RCEP
(ASEAN-Avustralya-Çin-Japonya-Güney Kore ve Yeni Zelanda)
*15 Kasım 2020 tarihinde imzalandı,
18 Mart 2022'de yürürlüğe girdi.

Trans-Pasifik Ortaklığı için Kapsamlı ve Aşamalı Anlaşma- CPTPP

*Eski adıyla Trans-Pasifik Ortaklığı Ticaret Paketi
(Yeni Zelanda, Avustralya, Brunei, Kanada, Şili, Japonya, Malezya,
Meksika, Peru, Singapur ve Vietnam)
*8 Kasım 2018 tarihinde imzalandı,
29 Kasım 2022'de yürürlüğe girdi.



Türkiye-Malezya Serbest Ticaret Anlaşması ve Genişleme Metni

Türkiye-Malezya Serbest Ticaret Anlaşması (STA) - 1 Ağustos 2015

MAL TİCARETİ

2023 → İhracatımızın %99'u, ithalatımızın ise %86'sı; gümrük vergisinden muaf

STA Genişleme Metni - 29 Eylül 2022

HİZMETLER

YATIRIMLAR

E-TİCARET

- Malezya'ya hizmet ihracatında (Örn: Savunma sanayi yazılımları, siber güvenlik, kriminal yazılımı vs.) kolaylıklar (lisans/izinlere dair düzenlemeler, makul ücretlendirmeler, açık mevzuat, itiraz yolları, dijitalleşme, süre kısaltımları, süreçlerde şeffaflaşma, çalışma/oturma izinlerinde kolaylaştırıcı/hızlandırıcı düzenlemeler, çoklu giriş vizesi imkanları vs.)
- Malezya'da yatırım yapmayı düşünen firmalar açısından çeşitli avantajlar (tahkim hakkı)





T.C. TİCARET
BAKANLIĞI

MALEZYA'DA YATIRIM ORTAMI VE TEŞVİKLER

Yabancı yatırımlar için asgari düzeyde kısıtlamalar
Yabancılara şirketlerde özkaynağın %100'üne sahip olabilme hakkı
Yabancılara serbest mülkiyet edinme hakkı

Malezya Uluslararası Ticaret ve Sanayi Bakanlığı'na (MITI) bağlı Malezya Yatırım Geliştirme Ajansı (MIDA)

(<https://www.mida.gov.my/>)

İstanbul Ofisleri faaliyete geçmiştir.

Mr. Sukri Abu Bakar
Foreign Investment Promotion Division
sukri@mida.gov.my

MIDA Avrupa Temsilcisi (İtalya):
Mr. Awangku Fiarulnazri Awang Tajudin
+39 02 8909 382 4
awangku@mida.gov.my

Yatırım Teşvikleri

I-Incentives portalı (<https://investmalaysia.mida.gov.my/incentives/>)

Havacılık, palm yağından elde edilecek katma değerli ürünler, endüstriyel yapı sistemleri, geri dönüşüm, otomasyon sistemleri, tarımsal üretim, enerji tasarruflu eşya, otomotiv, turizm, çevre yönetimi, yeşil teknoloji, arge, eğitim, sağlık turizmi, lojistik, soğuk zincir tesisleri, gaz ve radyasyon sterilizasyonu sektörlerinde faaliyet gösterecek yatırımlar Malezya hükümetince özellikle teşvik edilmektedir.

Eyalet bazlı Yatırım Ajansları

Invest Selangor, Invest KL vs.



Malezya'da Şirket Kurma

- Doğrudan yabancı ortaklı şirket kurulması
- Türkiye'deki şirketin şubesi şeklinde faaliyet gösterilmesi
- Temsilcilik ofisi açılması

İlk ikisine ilişkin işlemler SSM (Companies Commission of Malaysia) tarafından yürütülürken, üçüncü konuda Malaysian Investment Development Authority (MIDA) yetkilidir.

Müşavirliğimiz tarafından hazırlanan Malezya yatırım notuna [YATIRIM REHBERİ](#) linkinden ulaşabilmektedir.



T.C. TİCARET
BAKANLIđI

KAMU İHALELERİ

Malezya, Dünya Ticaret Örgütü Kamu Alımları Anlaşmasına taraf değildir. Malezya Hükümeti kamu alımlarında sistemi yerli firmalara öncelik tanıyacak şekilde düzenlenmiştir. İhalelere katılabilmek için Malezyalı yerli (%51 hissesi Bumiputra sahipli) bir firma ile ortaklık kurmak gerekmektedir.

Kamu İhaleleri:

<https://myprocurement.treasury.gov.my/>

<https://myprocurement.treasury.gov.my/iklan/tender/>



T.C. TİCARET
BAKANLIĞI

E-TİCARET



<https://www.lazada.com.my/>

<https://shopee.com.my/>



<https://pgmall.my/>

14 milyon e-ticaret kullanıcısı

2020 yılında 4 milyar 840 milyon ABD doları gelir

2025 yılına kadar yaklaşık 11 milyar ABD doları gelir beklentisi

Moda, elektronik ve medya, oyuncak, hobi ve kendin yap ürünleri, mobilya ve ev eşyaları, gıda ve kişisel bakım



MALEZYA`DA DÜZENLENEN FUARLAR

<https://10times.com/malaysia>

Gıda ve içecek alanında MIHAS Helal Fuarı, MIFB International Food & Beverage Trade Fair ile FHM Food and Hotel Malaysia fuarları

Savunma sanayi alanında DSA Defence Services Asia, LIMA Langkawi

Kozmetik alanında Beauty Expo ile Cosmobeaute Asia

Yenilenebilir enerji ve yeşil teknoloji sektöründe IGEM International Greentech & Eco Products Exhibition

Otomotiv sektöründe Automechanika fuarı

Mekanik ve elektrik sektöründe Asean M&E Show ile Malaysia Technology Expo (MTE)

İnşaat ve inşaat malzemeleri sektöründe, ARCHIDEX fuarı , International Construction Week ve Asean Super 8

Medikal sektöründe, Healthcare&Pharma Show, APHM Özel Hastahaneler Birliği Fuarı

Mücevher ve kuyumculuk sektöründe MIJF Malaysia International Jewellery Fair

Makine ve metal işleme sektörlerinde METALTECH ve Automex otomasyon teknolojileri fuarı

Mobilya sektörü için MIFF Malaysia International Furniture Fair

Su ve atık su alanında Asiawater

Turizm ve seyahat alanında Matta Fair




T.C. TİCARET
BAKANLIĞI

Malezya'ya İhracat İçin Ürün Bazında Gümrük Vergisi Sorgulama

<http://mysstext.customs.gov.my/tariff/>

(Google search: malaysia customs tariff)

← → ↻ Not secure | mysstext.customs.gov.my/tariff/

 **JKDM HS Explorer**
Jabatan Kastam Diraja Malaysia

Search HS Act and Order Contact Us

Search Tariff

Tariff Type
MTFTA

Search Criteria
HS Code

Keyword
080930

Search !!

MTFTA : Goods Under The Free Trade Agreement Malaysia- Turkey

* Click on description to see more information.

HEADER	SUB	ITEM	FULL HS	DESCRIPTION	CURRENT RATE
0809	30	0000	0809300000	-Peaches, including nectarines	0



T.C. TİCARET
BAKANLIĞI

Firma Bilgisi Doğrulama

Malezya'da şirket kayıtlarını tutan Companies Commission of Malaysia (SSM)'nin aşağıda sunulan internet sitesinden yararlanılabilir. Bu amaçla, doğrulama yapılabilmesini teminen firmalarımıza kolaylık olması açısından anılan siteden kullanıcı adı ve parola temin edilmiştir.

<https://www.ssm-einfo.my/index.php?id=login>

Kullanıcı adı

: ankara

Parola

: ANKARA07

ssm-einfo.my/index.php?id=login

SSM e-Info

Get Your SSM Documents!

Home About Us News Our Products Knowledgebase Help Center

If You're Always On-The-Go....
Go Mobile

Download on the App Store GET IT ON Google Play

Follow Us
f @ssmeinfo

Username: ankara
Password: *****
Image Verification: UTYCV
Enter word verification in the box below
*Case Sensitive
Log In



Search Now!

**Company &
Business Information**

Scanned Form Images

Customize List

Company Profile (ROC)

Business Profile (ROB)

Company Charges

Attestation of Company Good Standing

Financial Comparison

Particulars (Registered Address, Directors/Officers, Shareholders, Share Capital, Change of Company Name)

Business Expiry Confirmation Letter

Certificates of Incorporation of Private Company (1965/2016)

Certificates of Incorporation on Change of Name of Company

Shareholder Listing and Analysis

Search

Example :

Form 6 (Declaration of Compliance)

Form 8 (Certificate of Incorporation of Public Company)

Form 9 (Certificate of Incorporation of Private Company)

Form 102 (Memorandum & Articles of Associations)

Form 557 (Audited Financial Statement)

Form 559 (Annual Return)

Form 13A (Request for Availability of Name)

Form 24 (Return of Allotment of Shares)

Form 49 (Return Giving Particulars in Register of Directors, Managers and Secretaries and Changes of particular)

Search

Package A (Company Details)

Package B (Shares & Directors)

Package C (Profit & Loss)

Package D (Charges & Lodgement)

Search By Company

Search

By Registration Number

Search by 6-Digit Old BRN OR 12-Digit New BRN

NOTE: Type in **ONLY** the company registration number without '-' sign. **Example:499519**

Search

By Name

NOTE : Please enter the nearest keyword to optimize search time.

Search

Registration No	Name	Available Products	No (CTC)	Digital (CTC) Certified True Copy
199201004534 (236038-W)	PETRONAS ASSETS SDN. BHD.	Company Profile	Add to Cart	Add to Cart
		Company Charges	Add to Cart	
		Financial Comparison (2years)	Add to Cart	
		Financial Comparison (3years)	Add to Cart	
		Financial Comparison (5years)	Add to Cart	
		Financial Comparison (10years)	Add to Cart	
		Attestation of Company Good Standing	Add to Cart	
		Certificate of Incorporation of Private Company 1965	Add to Cart	Add to Cart
		Certificate of Incorporation on Change of Name of Company	Add to Cart	Add to Cart
		Particular of Registered Address	Add to Cart	
199601010462 (382811-T)	PETRONAS (E&P) OVERSEAS VENTURES SDN. BHD.	Company Profile	Add to Cart	Add to Cart
		Financial Comparison (2years)	Add to Cart	
		Financial Comparison (3years)	Add to Cart	
		Financial Comparison (5years)	Add to Cart	
		Financial Comparison (10years)	Add to Cart	
		Attestation of Company Good Standing	Add to Cart	
		Certificate of Incorporation of Private Company 1965	Add to Cart	Add to Cart
		Certificate of Incorporation on Change of Name of Company	Add to Cart	Add to Cart



T.C. TİCARET
BAKANLIĞI

Malezya Dış Ticareti Geliştirme Ajansı (MATRADE)



The Official Portal Of
Malaysia External Trade Development Corporation
The National Trade Promotion Agency of Malaysia

Matrade Türkiye Temsilciliği

Turkey (Europe)

Coverage

Armenia, Azerbaijan, Bulgaria, Georgia, Macedonia, Romania & Turkey

Address

MATRADE Istanbul
No. 76, 20th Floor
Buyukdere Caddesi
Maya Akar Center Plaza
34394 Esentepe, Istanbul
Turkey

Telephone

+90 212 217 8003

Fax

+90 212 217 8005

Email

istanbul@matrade.gov.my



Trade Commissioner
Mr. Zahiruddin Basiran



Assistant Trade Commissioner
Ms. Nur Syazana Abd Rahman



MALEZYA'DA İŞ YAPABİLMEK İÇİN...

- ✓ Malezya'nın orta-uzun vadede başarı getirecek bir pazar olduğu bilinmelidir.
- ✓ Sabırlı olmak ve işleyişin yavaş temposunu kabullenmek gerekmektedir.
- ✓ Kişisel ilişkiler kurmak önemlidir.
- ✓ Kamu ile iş yapacak firmalarımızın Malaylarla, özel sektörle iş yapacak olan firmalarımızın Çin asıllı Malezyalılarla muhatap olacağı unutulmamalıdır.
- ✓ Mümkünse temsilci bulundurmak, mümkün olmadığı durumlarda distribütör/acente ile çalışmak önemli avantajlar sağlamaktadır.
- ✓ Satış sonrası destek beklenmektedir.





Bakanlıđımızdan Faydalı Linkler

<https://www.kolayhracat.gov.tr/>

<https://kolaydestek.gov.tr/>

<https://ticaret.gov.tr/yurtdisi-teskilati/guney-dogu-asya/malezya/genel-bilgiler>

<https://distalep.ticaret.gov.tr/>



TÜRKİYE CUMHURİYETİ
TİCARET BAKANLIĞI

Sorularınız için
Müşavire Danışın Uygulaması:
<https://musaviredanisin.ticaret.gov.tr/>

E-posta adresimiz:
kualalumpur@ticaret.gov.tr

Teşekkürler



LICENSING/REGULATIONS & MARKET-ENTRY PROCESSES FOR PHARMACEUTICALS IN MALAYSIA

7 July 2023

Pharmaceutical Services Programme
Ministry of Health

BAHAGIAN PERKHIDMATAN FARMASI



Overview

1. Introduction
2. License relating to Pharmaceutical Product (Types of Licenses)

National Pharmaceutical Regulatory Agency (NPRA)	Pharmacy Enforcement Division (ENF)
a) Manufacturers License b) Import License c) Wholesalers License	a) Type A License



LICENSES VIA NPRA

3

PRODUCT REGISTRATION PROCESS

REGULATORY CONTROL OF PHARMACEUTICALS



CLINICAL TRIALS

Vaccines undergo extensive testing through several phases of trials:

Pre-clinical studies: tissue-culture/ animal studies.

Phase I clinical trials: small-scale trials in 20-100 healthy adult volunteers to assess initial safety and responses.

Phase II clinical trials: larger, target age group(s). Assess the efficacy, safety and immune response.

Phase III clinical trials: studies on a large scale, in thousands of subjects across several sites.

PRE-REGISTRATION

Dossier Evaluation

- Administrative Data/ Documents, Quality, Non-clinical, **Clinical data**
- Experts Inputs
- GMP Inspections
- Guidance Doc (DRGD)/ WHO/ EMA

DCA (PBKD): Approval based on evaluated evidence

POST-REGISTRATION

Lot Release

Post Marketing Surveillance

Pharmacovigilance (including AEFI/ADR Monitoring)

Post-Approval changes



HOW IS MEDICINAL PRODUCTS REGULATED IN MALAYSIA

Control of Drugs and Cosmetics Regulations 1984, Regulation 7(1) states that:

“Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import, possess or administer any product unless:

- a) the product is a registered product; and
- b) the person holds the appropriate licence required and issued under these Regulations.”

Registration

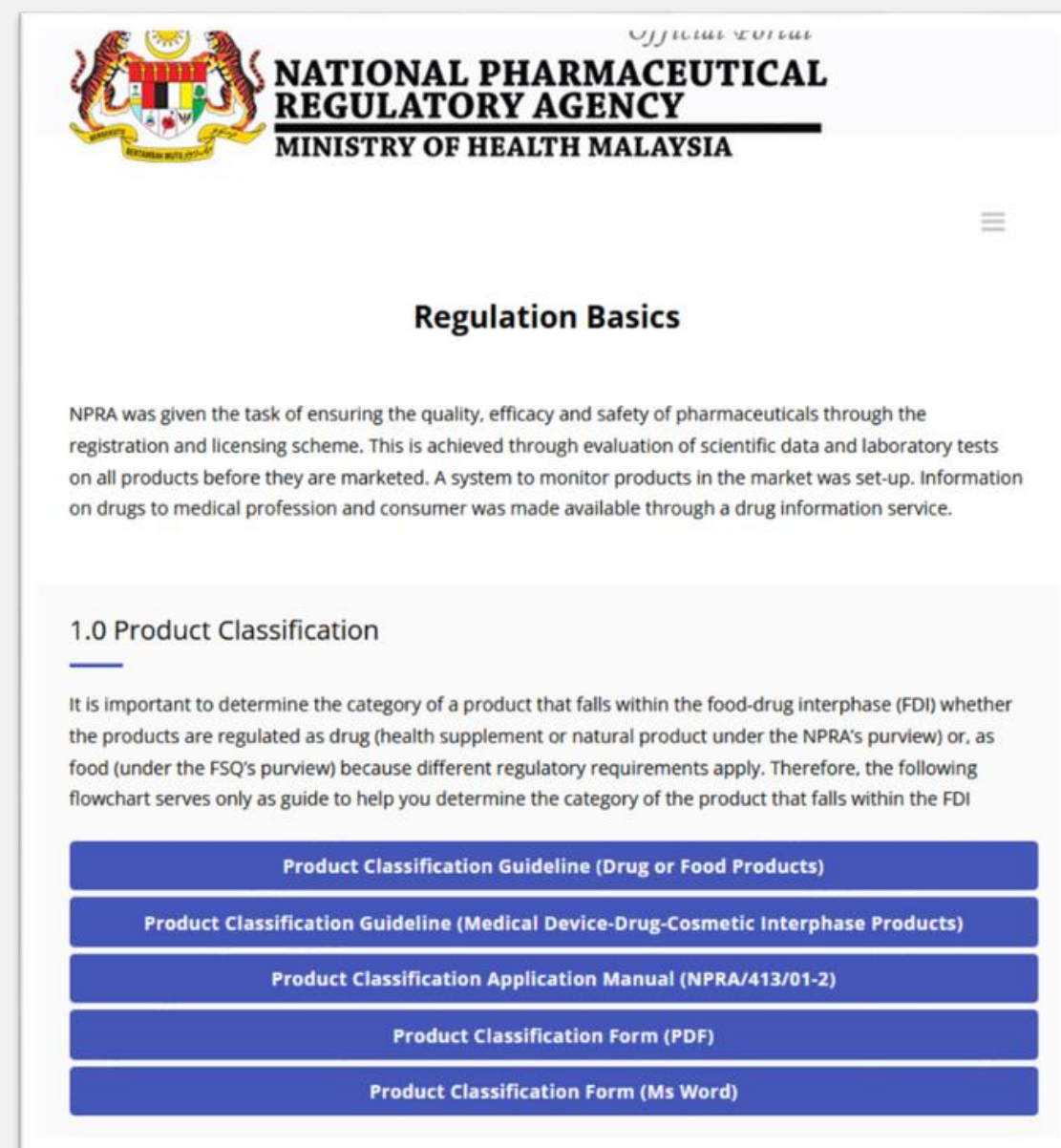
Any product that fits the definition of medicinal product requires registration with the Drug Control Authority (DCA).

Product Classification

Applicant may submit a classification form if they are:

- Unsure if their product meets the “product definition”
- Unsure of the product category

Classification Form available on NPRA website.



NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

Regulation Basics

NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. This is achieved through evaluation of scientific data and laboratory tests on all products before they are marketed. A system to monitor products in the market was set-up. Information on drugs to medical profession and consumer was made available through a drug information service.

1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

- [Product Classification Guideline \(Drug or Food Products\)](#)
- [Product Classification Guideline \(Medical Device-Drug-Cosmetic Interphase Products\)](#)
- [Product Classification Application Manual \(NPRA/413/01-2\)](#)
- [Product Classification Form \(PDF\)](#)
- [Product Classification Form \(Ms Word\)](#)



PRODUCT CATEGORIES



WHO SHALL APPLY FOR PRODUCT REGISTRATION?

Product Registration Holder (PRH)

The applicant for product registration (known as PRH) must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia (Suruhanjaya Syarikat Malaysia (SSM)) (with business scope related to the health/pharmaceutical product).

If the applicant is not the product owner,

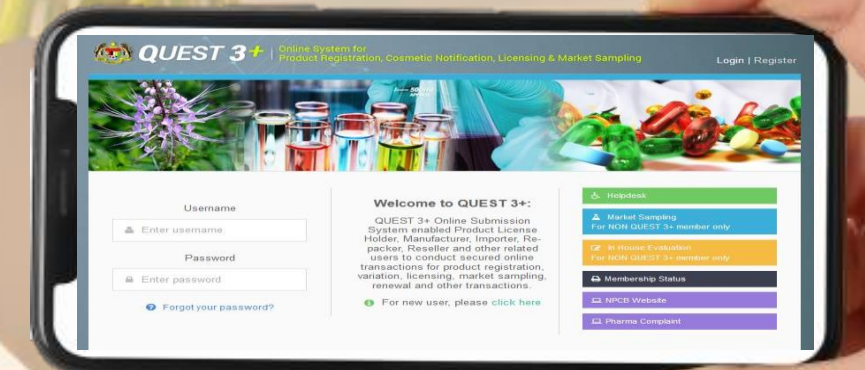
the product owner shall authorize the PRH in writing to be the holder of the product registration who is responsible for all matters pertaining to the quality, safety and efficacy of the product. This includes the responsibility to update any information relevant to the product / application.

How to apply?

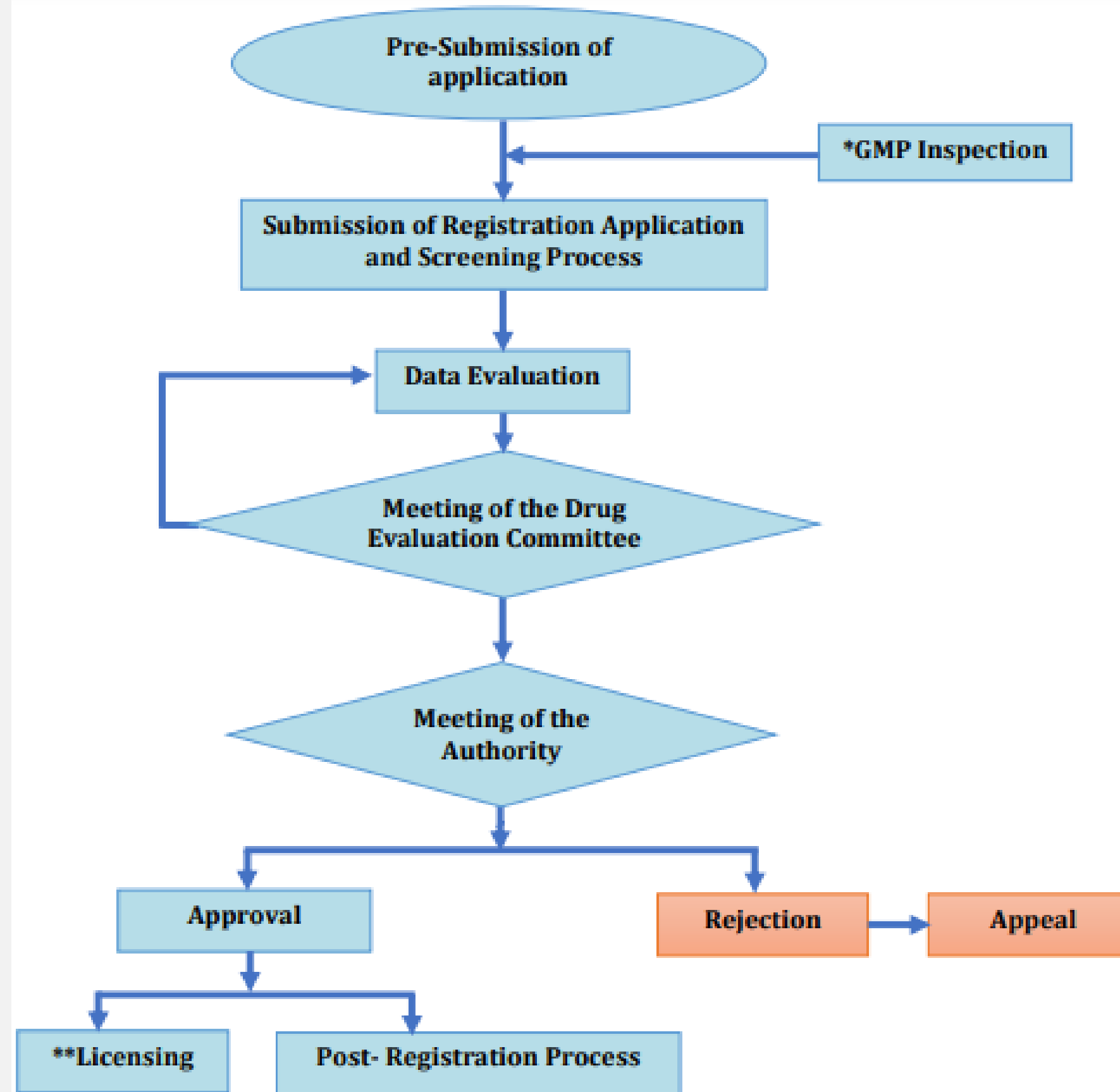
01 QUEST Membership

- Register for QUEST membership
- Purchase USB Token

02 Web-based Online Submission



PRODUCT REGISTRATION PROCESS



* Good Manufacturing Practice (GMP) Certification
** Application for Manufacturer's, Import and/or Wholesaler's License



**Drug Registration
Guidance Document
(DRGD)**

The related GMP guidelines referred are:

PIC/S Guide to Good Manufacturing Practice for Medicinal Products

PRODUCT TYPE/CATEGORY

- Pharmaceuticals (Poison and NonPoison)
- Veterinary Medicinal Products
- Investigational Medicinal Products
- Active Pharmaceutical Ingredients

GMP Guideline for Traditional Medicines and Health Supplements, 1st Edition, 2008

PRODUCT TYPE/CATEGORY

- Traditional Products
- Health Supplements

Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes, 1st Edition, January 2015

PRODUCT TYPE/CATEGORY

Veterinary Products
(Premixes)

Guidelines on Good Manufacturing Practice (GMP) for Cosmetics (Annex I, Part 10)

PRODUCT TYPE/CATEGORY

Cosmetics

FOREIGN GMP INSPECTION

The PRH must provide acceptable evidence to prove that the manufacturer of the product follows an internationally accepted standard of GMP and recognized by the Authority in Malaysia.

The CDCR 1984 requires that the standard of manufacturing and quality control of medicinal products manufactured outside Malaysia be taken into consideration before the products are registered with the Authority.

Hence, foreign manufacturers are also subjected to GMP conformity assessments through acceptable GMP evidence or GMP inspection.



National Pharmaceutical Regulatory Agency (NPR)
Ministry of Health Malaysia

Lot 36, Jalan Prof. Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor.
Tel. No. : 03-78835400
Website : <http://npra.gov.my>

GUIDANCE DOCUMENT
FOREIGN GMP INSPECTION

9th Edition
March 2023

TYPES OF LICENSES

- 01** **Manufacturer's License:** Licensee is authorized to manufacture the registered products in the premises specified in the license and to sell by wholesale or supply the products
- 02** **Import License:** Licensee is authorized to import and sell by wholesale or supply the registered products from the address of the premises specified in the license.
- 03** **Wholesaler's License:** Licensee is authorized to sell by wholesale or supply the registered products from the address of the business premises specified in the license



TIMELINE

NO	PRODUCT CATEGORY	EVALUATION TIMELINE
(A)	FULL EVALUATION	
1.	New Drug Products (NCE)	245 working days
2.	Biologics	
3.	Natural Products with Therapeutic Claim	
4.	New Drug Products (Hybrid)	210 working days
5.	Generics (Scheduled Poison)	
6.	Generics (Non-Scheduled Poison)	
(B)	ABRIDGED EVALUATION	
7.	Generics (Non-Scheduled Poison) a) Single active ingredient b) Two (2) or more active ingredients	a) 116 working days b) 136 working days
8.	Natural Products a) Single active ingredient b) Two (2) or more active ingredients	a) 116 working days b) 136 working days
9.	Health Supplements a) ** Single active ingredient b) ** Two (2) or more active ingredients <i>**Applicable for: i) General or Nutritional Claims; and ii) Functional Claims (Medium Claims)</i>	a) 116 working days b) 136 working days
	c) Disease Risk Reduction Claims (High Claims)	c) 245 working days

FEES

Product Registration Fees

No.	Category of Product	Total Fees (RM)	
		Single active ingredient	Two or more active ingredients
1.	Pharmaceutical (New Drug Products / Biologics)	4,000	5,000
2.	Pharmaceutical (Generic / Health supplement)	2,200	3,000
3.	Natural Product	1,200	
4.	Natural products with therapeutic claim	4,000	5,000

License Application Fees

No.	License	Processing Fees (RM)
1.	Manufacturer's	1,000.00
2.	Import	500.00
3.	Wholesaler's	500.00

Fees for USB Token

Type	Validity Period	
	1 year (RM)	2 year (RM)
Main User (Certificate + USB Token)	260	290
Postage	Semenanjung - 10 Sabah/Sarawak - 20	




LICENSES VIA PHARMACY ENFORCEMENT





LICENSING REQUIREMENTS UNDER THE POISONS ACT 1952 FOR PHARMACEUTICAL INDUSTRY IN MALAYSIA

1. Poisons Act 1952 control importation, sale or supply of poisons under the **First Schedule (Poisons List)** of the Act.
2. The importer and/ or wholesaler/ supplier of pharmaceutical products containing poison required to hold a valid **Type A licence** under the Act.

- 
3. **Type A Licence** : issued to a **pharmacist to import, store and deal generally all poisons** by ‘wholesale and retail’ or by ‘wholesale only’ or by ‘retail only’.

 4. Main requirements for Type A Licence application :
 - i. **Registered pharmacist in Malaysia**
 - ii. **Registered business/ company in Malaysia**
 - iii. **Comply Community Pharmacy Benchmarking Guideline (for community pharmacy only – Type A licence for retail activity).**

- 
5. **Guidelines** for Application of Type A Licence **available at** www.pharmacy.gov.my (*Document & Media » Documents » Guidelines*).
 6. Application is online through system My.Pharma-C
 7. Fee : RM 300
 8. **Subject to inspection** of the premise before approval to ensure compliance with the requirements under the Poisons Act 1952.
 9. Client charter : Issuance of Type A Licence within seven (7) working days upon receipt of **complete application (including premise ready to be inspect)**.



10. The distribution of pharmaceutical products containing poison **by wholesale** only can be done by a licenced wholesaler (**Type A licence for wholesale activity**) to those listed under section 15(2) Poisons Act 1952.

11. The **retail supply** of pharmaceutical products containing poison for medical treatment can be done by :

- i. Registered medical practitioner in accordance to section 19 Poisons Act 1952; Or
- ii. Licenced pharmacist (**Type A licence for retail activity**) in accordance to section 21 and 22 of the Poisons Act 1952.

The image shows the exterior of a building with a sign that reads "BAHAGIAN PERKHIDMATAN FARMASI KEMENTERIAN KESIHATAN MALAYSIA". A large yellow "THANK YOU" text is overlaid on the image. The building has a modern design with a covered entrance and a blue signpost in the foreground. The signpost also features the text "BAHAGIAN PERKHIDMATAN FARMASI" and a logo. The building is surrounded by trees and a paved area.

THANK YOU

Pharmaceutical Services Programme
Ministry of Health

INFORMATION PRESENTATION ON LICENSING/ REGULATIONS, MARKET-ENTRY PROCESSES



INTRODUCTION TO THE MEDICAL DEVICE REGULATORY SYSTEM IN MALAYSIA

BY MEDICAL DEVICE AUTHORITY, MOH



➤ **OVERVIEW OF THE MEDICAL
DEVICE INDUSTRY IN
MALAYSIA**

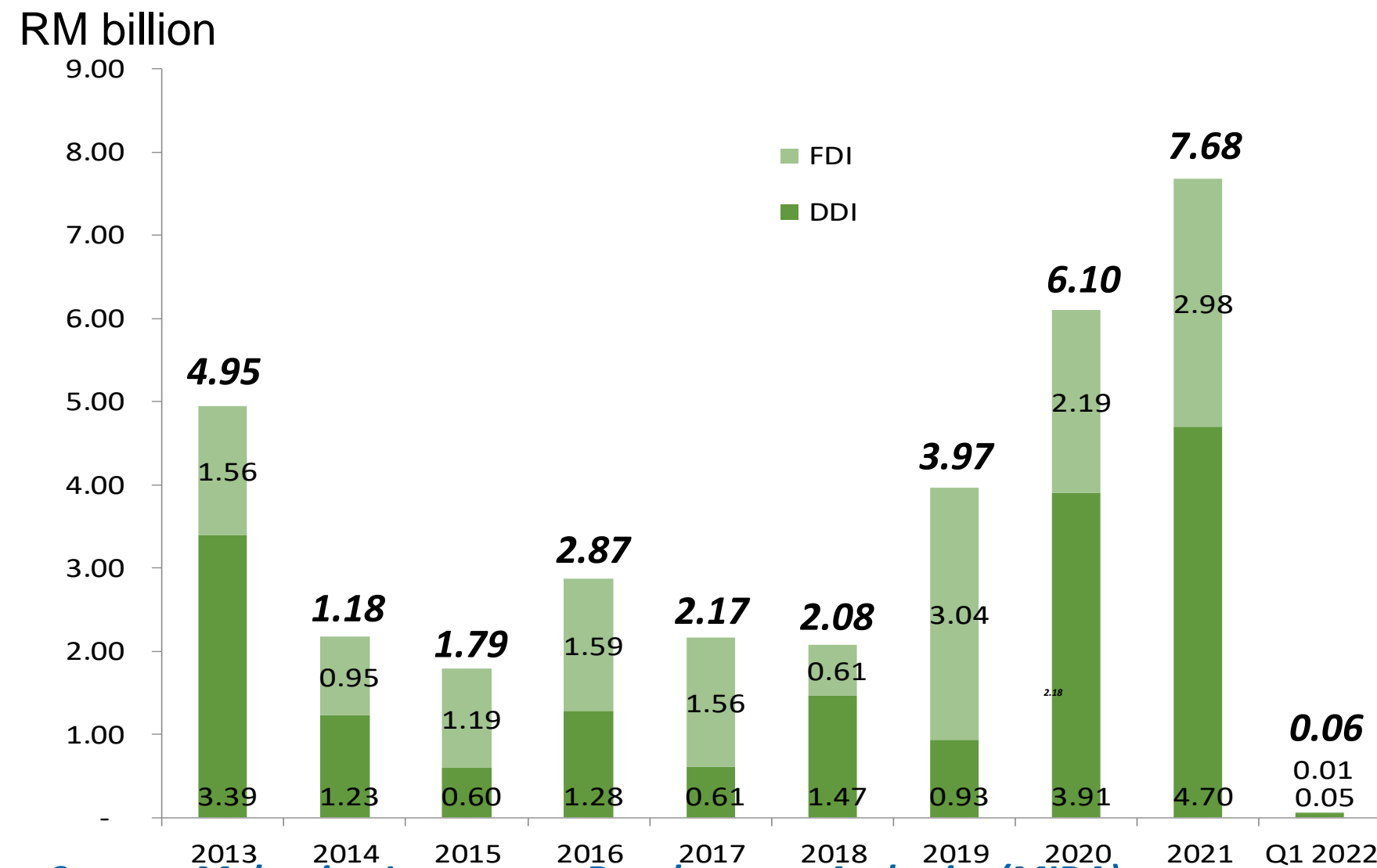
➤ **OVERVIEW OF MEDICAL
DEVICE REGULATORY
REQUIREMENT IN MALAYSIA**

- Medical Device Act 2012
- Regulations
- Other documents



INVESTMENT PERFORMANCE IN MEDICAL DEVICES INDUSTRY

Approved Investment from 2013-March 2022



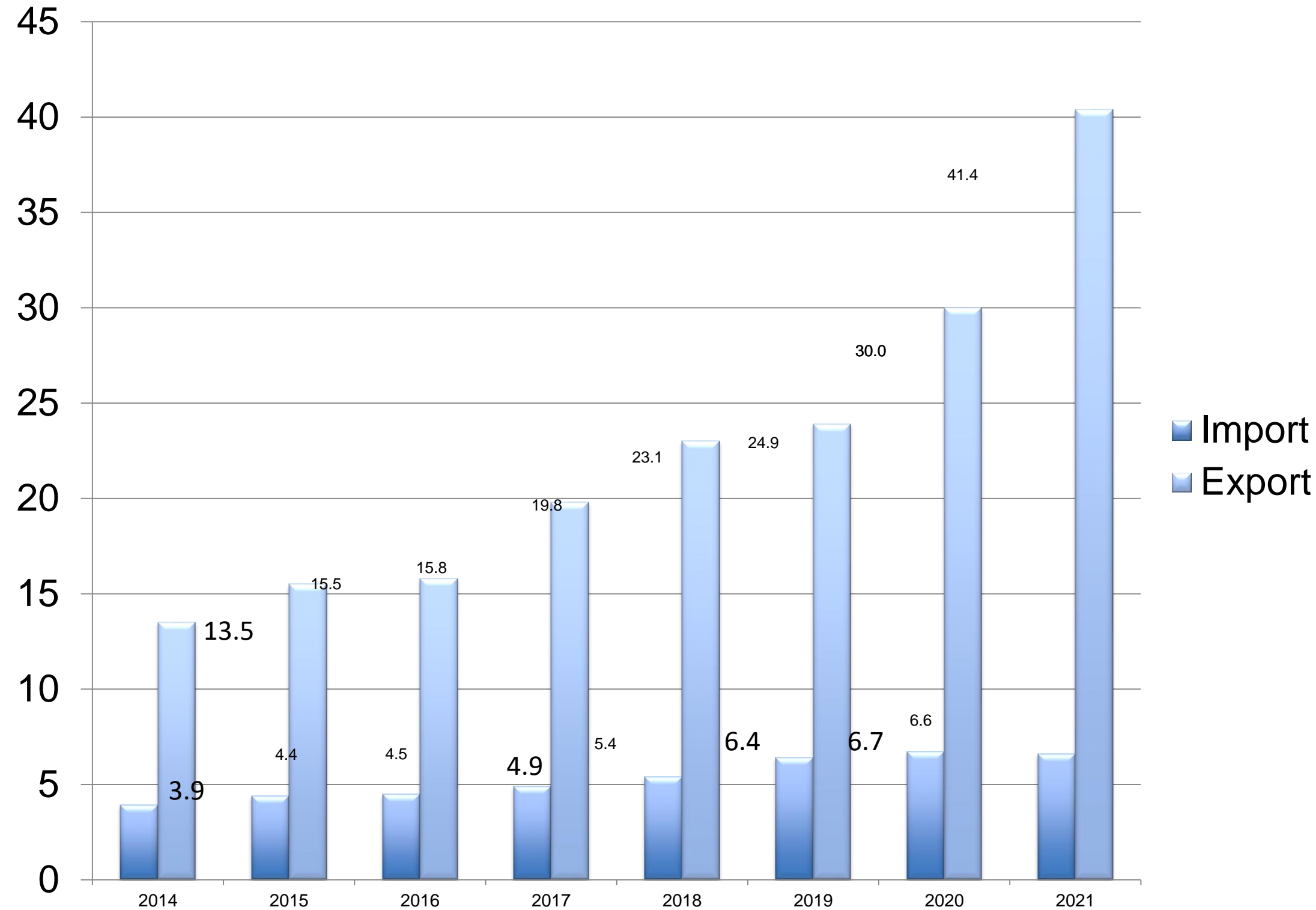
Source: Malaysian Investment Development Authority (MIDA)

Among major companies in Malaysia (in operation)



TRADE PERFORMANCE IN MEDICAL DEVICES INDUSTRY

RM' Billion



Top 3 export destinations : USA, Europe (Germany & Belgium) and Japan.

Top 3 import countries: USA, China and Germany

Major products exported : Surgical and examination gloves; needles, catheters, cannulae; instruments & appliances used in medical or veterinary; Orthopedic & other appliances, worn, carried or implanted in the body; and; Electro-diagnostic apparatus.

Major imported products : Intravenous, contact lenses disposable tubes for intravenous, Cannules, Orthopaedic appliances



Overview of Medical Device Regulatory Requirements In Malaysia

Objectives



To address matters of public health & safety

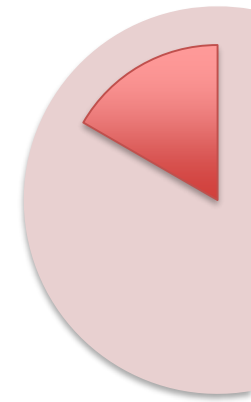
- pre-market control to assess safety, effectiveness and quality of medical devices
- adequate information for the public and health professionals to make informed choices on medical devices
- control over the usage of certain medical devices
- post-market reporting system to identify and monitor continued safety of medical devices and address issues



To facilitate the medical device industry

- To facilitate our local manufacturers in creating a level playing field with global players
- To provide a favourable environment for the growth of medical device industry
- To facilitate industry players in complying with regulatory requirements.

MALAYSIA MEDICAL DEVICE REGULATORY FRAMEWORK



CONFORMITY ASSESSMENT

- Quality Management System (ISO 13485)
- Post Market Surveillance System
- Technical Documentation
- Declaration of Conformity

Pre-market

CAB verifies evidence of conformity



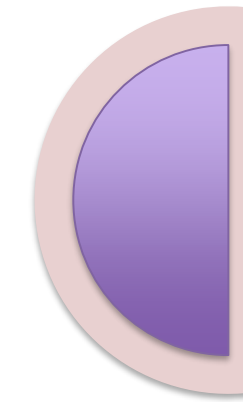
MEDICAL DEVICE REGISTRATION

- Assurance of safety & performance of medical device
- Marketing approval

ESTABLISHMENT LICENSING

- Compliance to Good Distribution Practice (GDP) & advertising requirements
- Approval to import / export / distribute medical devices

Placement on Market



SURVEILLANCE & VIGILANCE

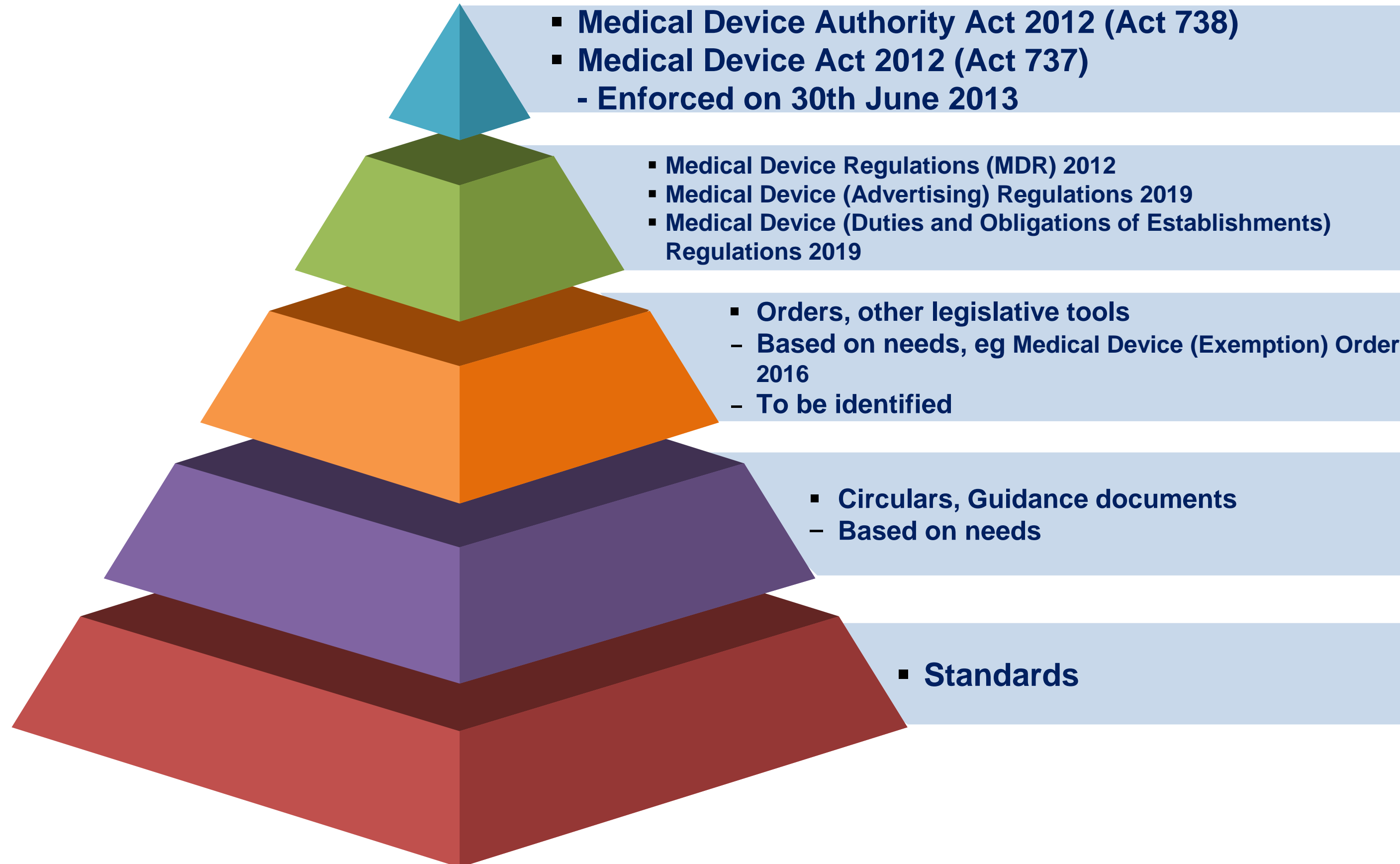
- Monitoring of safety & performance of medical device
- Carry out post-market obligations (complaint handling, incident reporting, Field Corrective Action (FCA), recall)

Post-market

USAGE & MAINTENANCE

- Use, maintain & dispose off medical devices appropriately
- Apply for permit to use/operate designated medical devices

Hierarchy of Legal Documents



IMPORTANT REGULATORY ACTIVITIES

**Section 5
Act 737**

- Medical device **Registration**

**Section 15
Act 737**

- Medical device **Establishment License**

**Chapter 3
Act 737**

- **Post Market Surveillance & Vigilance**
- MDR 2019 + guidance documents

CONFORMITY ASSESSMENT PROCESS

CONFORMITY ASSESSMENT BODY

Under Medical Device Act 2012 (Act 737):

- 10. (1) A conformity assessment body shall be a body registered under this Act to carry out conformity assessment of a medical device to be registered under this Act.

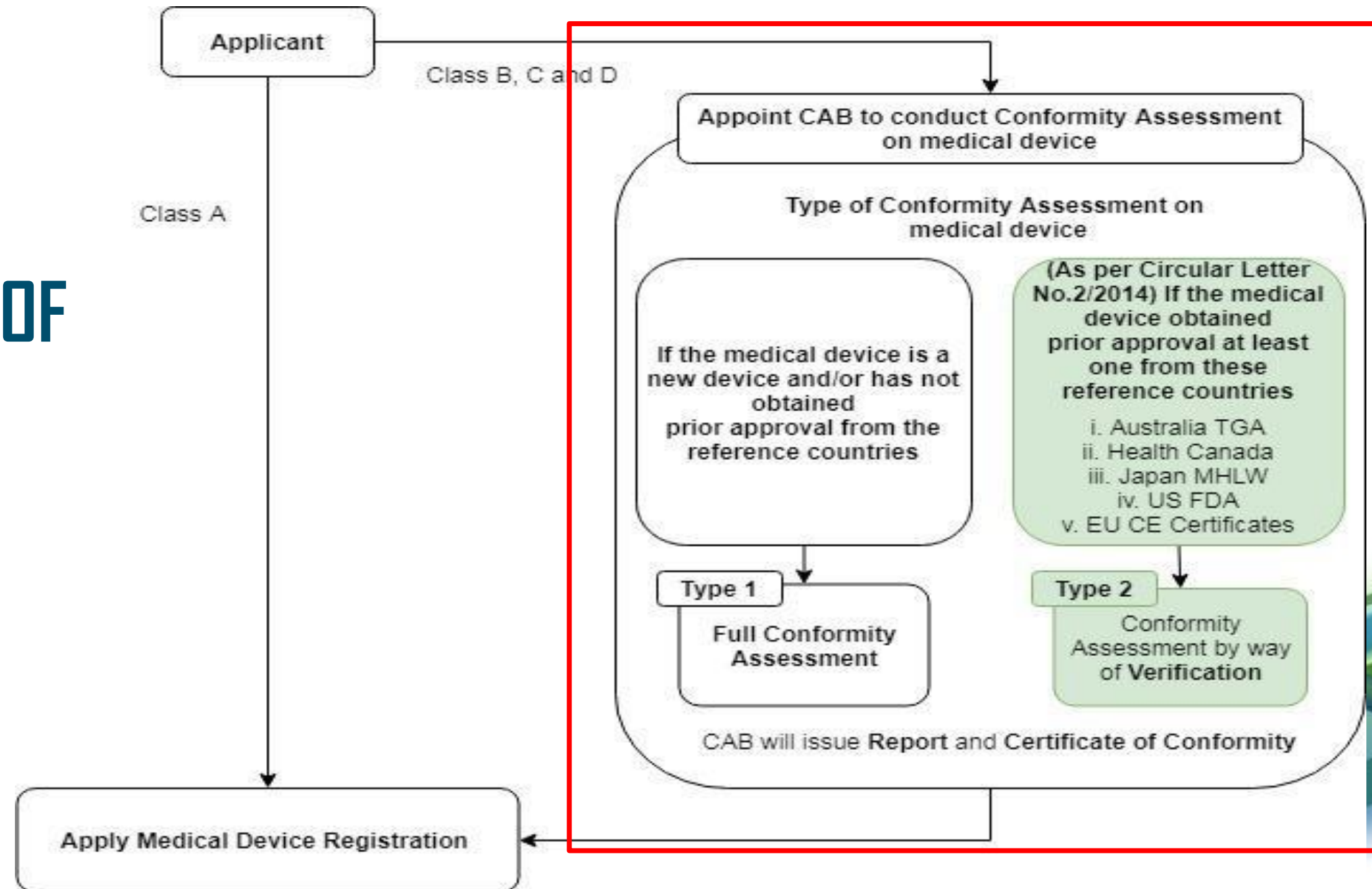
REQUIREMENT FOR REGISTRATION OF CONFORMITY ASSESSMENT BODY

Under Medical Device Act 2012 (Act 737):

- 11. (1) No conformity assessment body may carry out any conformity assessment related to a medical device unless it is registered under this Act

- Conformity Assessment as prescribed in **Third Schedule of MDR 2012**

- Conformity Assessment by way of Verification as described in **Circular Letter of the Medical Device Authority No. 2 Year 2014.**



ELEMENTS OF CONFORMITY ASSESSMENT

CAB TO CONDUCT CONFORMITY ASSESSMENT ON THESE ELEMENTS:

i. Quality Management System

Manufacturer	ISO13485
Authorised Representative	GDPMD
Importer	GDPMD
Distributor	GDPMD

ii. Post-Market Surveillance System

- Established, maintained and implemented by the manufacturer

iii. Technical Documentation

- Common Submission Dossier Template (CSDT), Essential Principal of Safety and Performance (EPSP), etc

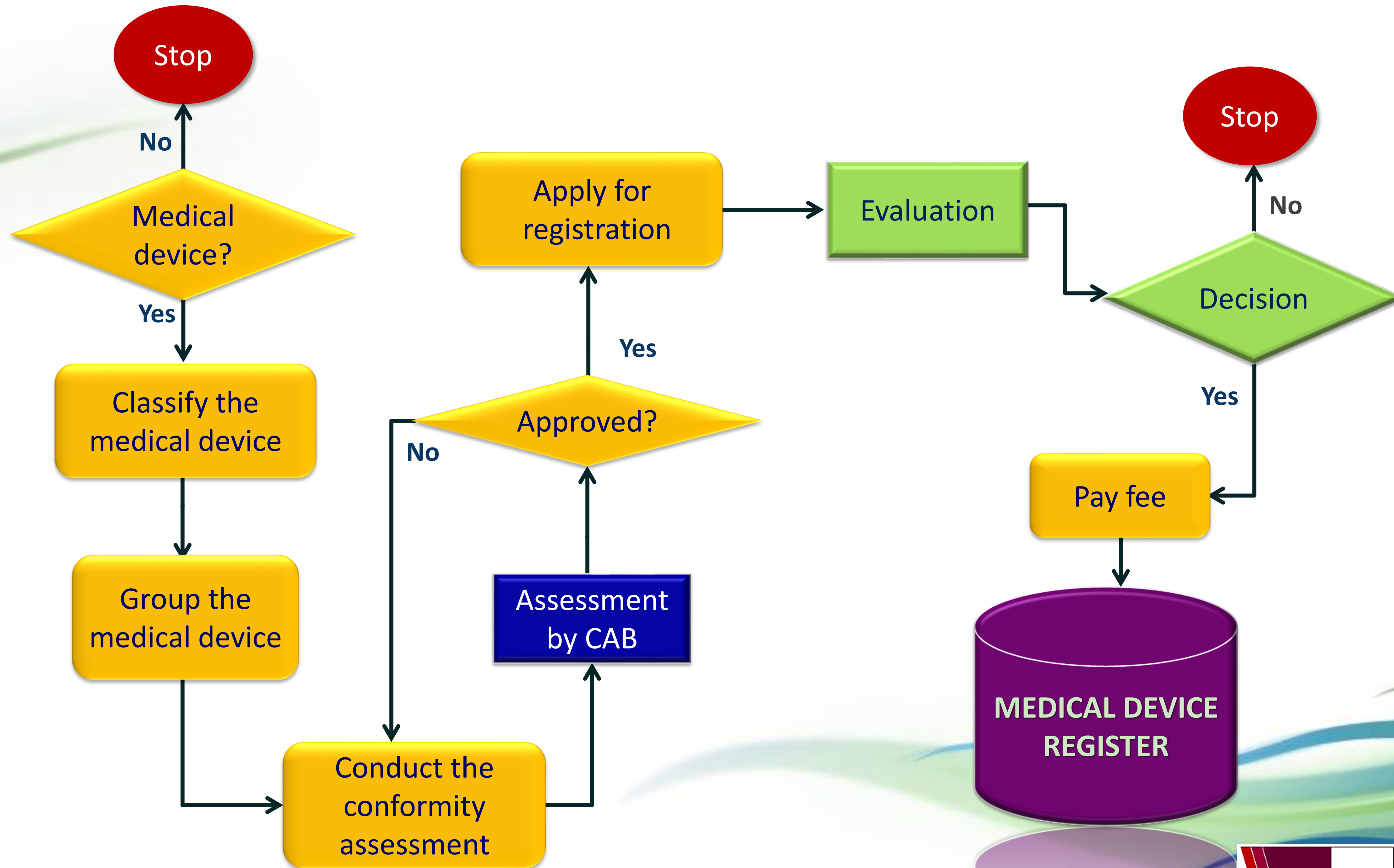
iv. Declaration of Conformity (DoC)

REGISTRATION OF MEDICAL DEVICES

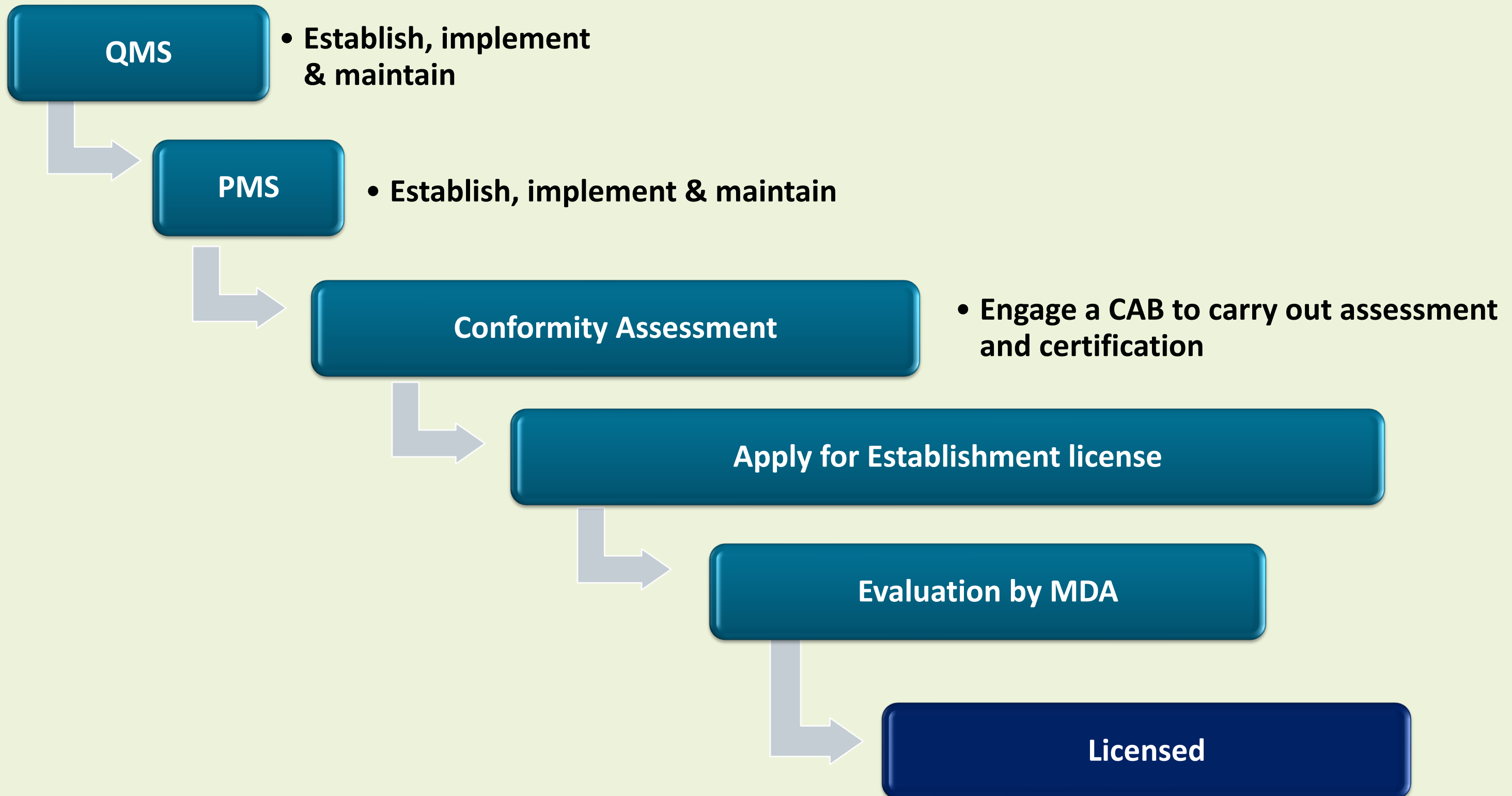
- Medical device regulatory system is based on **safety & performance of medical devices** throughout their life cycle
- Prior to registration of a medical device, **CA is conducted to provide objective evidence of safety & performance** a medical device
- Only registered medical devices can be placed into the market
- Establishments dealing with medical devices **must comply with conditions and carry out their obligations**

- **Who shall be responsible?**
 - Licensed local manufacturers or authorized rep
- **Conformity assessment elements:**
 - Submission of CSDT
 - Submission of DoC
 - Establishment, maintenance and making available of QMS
 - Post market system
- Upon approval, the medical device will be listed in the Medical Device Register (MDAR)

MEDICAL DEVICE REGISTRATION OVERVIEW



ESTABLISHMENT LICENCE PROCESS



NEW POLICIES

1. Withdrawal of Circular Letter No. 1/2014 effective 17 June 2021

- Allows for registration of a medical device **by multiple Authorized Representatives**, effective 17 June 2021

- However, the implementation of a **single license for each activity/role** of an establishment will be postponed to a later date, which has yet to be decided in view of the pandemic situation.

2. Full registration of COVID-19 Self-test Kit

3. E-permit application system for importation of medical devices following gazettelement of Customs Prohibition Order.

Exemption of MD via CA/SA to Full Registration

The Covid-19 assessment Committee Of experts has agreed that all Covid-19 test kit applications pending **Conditional Approval and Special Access** would be halted and that all future applications will be submitted using the Medcast online system. The deadline for applications pending in CA and SA is set for March 3rd, 2022. As a result, all establishments must submit an application through the Medcast system ([MeDC@St 2.0](mailto:MeDC@St2.0)).

Please refer to COVID application MDA guideline and Guidance Document Guideline (MDA/GL/MD-01, MDA/GL/IVD-1, MDA/GL/07 and MDA/GD/0059).

MDA/GL/07
January 2022
Second Edition

GUIDELINE FOR REGISTRATION OF
COVID-19 IVD TEST KITS

CIRCULAR LETTERS

[Home](#) [Introduction](#) [Division](#) [FAQ](#) [Contact Us](#) [Documents](#) [Counter Appointment](#)

[Home](#) / [Documents](#) / [Circular Letter](#)

Circular Letter Of The Medical Device Authority

Circular Letter Of The Medical Device Authority

In view of the problems faced by stakeholders, and an effort to facilitate the industry, Medical Device Authority (MDA) has taken into account the issues raised. After much deliberation the Authority has decided to alleviate and remove all obstacles in the implementation of Medical Device Act (Act 737) as part of our continued role in facilitating the industry.

We are pleased to inform that MDA has decided on new policies to facilitate the stakeholder and industry in the implementation of Medical Device Act (Act 737).

The policies are as follows:

NO	TITLE	LANGUAGE
1/2014	Establishment As Authorised Representative And Establishment Undertaking Multiple Activities (Withdrawn)	Malay / English
2/2014	Conformity Assessment Procedures For Medical Device Approved By Recognised Countries (Appendix 1-Revision 4)	Malay / English
3/2014	Exemption Of Medical Device From Registration Requirements Note:The Circular Letter will no longer effective. Please Refer to Medical Device Exemption 2016	Malay / English
4/2014	Medical Device For Import / Export From / To Countries Without Diplomatic Ties With Malaysia	Malay / English
5/2014	Certification Of Good Manufacturing Practice (GMP) For The Purpose Of Obtaining Establishment License	Malay / English

UPDATE ON PUBLICATIONS OF GUIDANCE DOCUMENTS

MDA/GD/0032
March 2021
Second Edition

**MEDICAL DEVICE
GUIDANCE DOCUMENT**

CODE OF ADVERTISEMENT (COA)

- 42 guidance documents have been published in MDA website.
- As of March 2023, 3 guidance documents published:
 1. MDA/GD/0057, Medical Gas System-Requirements for Registration (Second Edition);
 - Revised to include the classification rule and class for gas cylinder without medicinal gas
 2. MDA/GD/0061, Classification of Rehabilitation, Physiotherapy and Speech Therapy Device (Second Edition);
 - Rephrased the information of medical device classified as rehabilitation, physiotherapy and speech therapy device in Annex A
 - Include examples of medical devices classified as rehabilitation, physiotherapy and speech therapy device in Annex B
 3. MDA/GD/0064, Notification of Custom-made Medical Device(First Edition).
 - New guidance document to specify the notification requirements
- List of guidance documents in progress: 7

INDUSTRY FACILITATION

MEDICAL DEVICE NOTIFICATION

- Special Access
- Custom-Made
- Demonstration for Marketing & Education
- Export Only
- Import for Re-Export

INDUSTRIAL ASSISTANCE

- MDA-Industry Collaborative Committee-MICC
- Industry Engagement
- Enquiry Management

MEDICAL DEVICE IMPORT PERMIT

- Product Verification
- Import Permit

MDA issues “no restriction for importation” letters, confirmation letter & permit, to facilitate medical device trade & industry : global market & growth of the industry

MEDICAL DEVICE IMPORT PERMIT

- MDA is in the process of inserting all products that are regulated under Act 737 into **Customs (Prohibition of Imports) Order 2017** – medical devices are to be gazetted as controlled items under *Part II of Fourth Schedule.
- Application and approval will be performed electronically through an ePermit System. Only registered user is allowed to have an access to the ePermit system.
- Permit approved by MDA will be linked to Sistem Maklumat Kastam (SMK) for Custom Declaration (CusDec) declaration purposes.
- In Malaysia, the National Single Window (NSW) for Trade Facilitation system is developed, operated and managed by Dagang Net Technologies Sdn Bhd (Dagang Net).

Industrial Assistance

MDA-Industry Collaborative Committee - MICC

- The committee formed in 2020;
- Committee members :
 - Association of Malaysian Medical Industries (AMMI),
 - Malaysia Medical Device Association (MMDA),
 - Malaysian Rubber Glove Manufacturers Association (MARGMA),
 - Malaysia Dental Industry Association (MDIA),
 - Persatuan Perkilangan Peranti Perubatan (PERANTIM).

Industrial Assistance

❑ Medical Device Industry

Engagement

- Partnership with medical device industry
 - Adopting Collaborative relationship,
 - jointly consider options,
 - Creating transparency between MDA and industry
- MDA role: to ensure that medical device industry is adhering to agreed rules

❑ Enquiry Management

- Responding to medical device industry enquiries
- To deliver accurate information to all incoming enquiries

Consultation Services

- **Consultation services** (industry players and other stakeholders may request for consultation sessions on regulatory matters).
- Other industry facilitations such as issuance of **certificate of free sales (CFS)**/ **Manufacturing Certificate (MC)** for the exportation of medical devices out of Malaysia.
- Undertaking **competency** activities related to installation, testing, commissioning, maintenance and disposal of medical devices.

The screenshot shows the official portal of the Medical Device Authority (MDA) of Malaysia. The header includes the MDA logo, the text "Official Portal Medical Device Authority Ministry of Health Malaysia", and a red banner with the hotline number "+603 - 8230 0300". The navigation menu contains "Home", "Introduction", "Division", "FAQ", "Contact Us", "Documents", and "Counter Appointment". Below the menu are four main user categories: "PUBLIC", "INDUSTRY", "PROFESSIONAL", and "MDA STAFF". A large banner in Malay encourages users to register their medical devices with MDA, providing the URL <https://mdar.mda.gov.my/>. The main content area is divided into four sections: "News", "Safety Information", "e-Services", and "Satisfaction Survey". The "e-Services" section features several logos, with "Public Search" and "DAFEMES" highlighted by red circles. The "Satisfaction Survey" section includes a graphic with speech bubbles for "Good", "Nice", and "Like", and a "Click to answer" prompt.

Official Portal
Medical Device Authority
Ministry of Health Malaysia

Our Hotline ☎ +603 - 8230 0300

Home Introduction Division FAQ Contact Us Documents Counter Appointment

PUBLIC INDUSTRY PROFESSIONAL MDA STAFF

Pihak Berkuasa Peranti Perubatan (MDA)
Kementerian Kesihatan Malaysia

JADILAH
PENGUNA BIJAK

**BELILAH PERANTI PERUBATAN
YANG BERDAFTAR DENGAN MDA**

Sila semak melalui sistem carian awam MDA di pautan: <https://mdar.mda.gov.my/>

AND

News 1 2 3 4 5

Safety Information

The following documents are summary of some medical device safety information related to potentially hazardous cases. It only serves as a quick reference and in no way should be considered as exhaustive and up-to-date. Please refer to the source of information and your product supplier for details.

For Listing of Recalls & Listing of Field Safety Notice, please [Click Here!](#)

e-Services

Public Search MEDC@St20+
Medical Device Authority Register (MDAR) MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

MeDTComp CFS/MC

DAFEMES Regulatory Information Subscription RIS

MeDCRes+

Satisfaction Survey

Your Satisfaction is Our Goal

Excellent Good Nice Like

Click to answer



<https://femes.mda.gov.my/index.php>

THANK YOU

Any question?

For further information:

Book your appointment via

consultation@mda.gov.my

**Policy, International Affairs & Industry Facilitation
Division**

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