菲律賓醫療器材法規及市場簡介

駐菲律賓代表處經濟組彙整

壹、 菲律賓醫療器材法規

一、 上市前須向FDA註冊:菲國主管醫材單位係菲國衛生部食品藥物管理局(Food and Drug Administration，簡稱FDA)，所有國外進口醫療器材不論是否有在其他國家註冊，都必須要通過菲國的註冊程序。依據菲國衛生部行政命令No.2007-0003醫材註冊及認證規定，未經FDA首長批准及簽名，不得發放設備註冊證明、製造證明、進口、出口、銷售等許可證。首次申請需180工作天，需支付1515披索。詳細註冊流程如附表1。

二、 必須強制註冊之醫療器材項目:依據菲國FDA備忘錄No.2014-005，菲國規定強制註冊醫療器材項目區分為醫材(Medical Device)及體外診斷醫療器材(In Vitro Diagnostic Medical)。醫材方面，包括:腹墊、可吸收止血劑、繃帶等180項；體外診斷醫療器材方面，包括:抗體或抗原試劑盒等8項。(詳如附件2)

三、 提供註冊文件:欲在菲國取得產品註冊登記，需在菲律賓設立公司或透過可靠的經銷商，並提供下列註冊文件，向菲國 FDA 取得證書。

(一) 醫材(Medical Device)註冊文件(詳如附件 3):1. 經銷商(進口商/出口商/批發商/本地製造商/貿易商)的公證申請表；2.有效經銷商(進口商/出口商/批發商/本地製造商/貿易商)營業許可證；3.經過菲律賓領事館認證的產品進口許可證與自由銷售證；4.進口品，經過菲律賓領事館認證之製造商 ISO 證書；5. 國外製造商與菲律賓當地經銷商的有效的外國代理協議(Foreign Agency Agreement)；6.產品使用說明；7.產品原料，必須包含數量及每種成分的物理及化學特性;8 產品生產、加工、包裝過程說明；9.產品技術規格與外觀描述說明書；10. 產品穩定性測試報告；11.產品商標標示及標籤說明；12.產品樣本；13.繳納登記費用的證明。

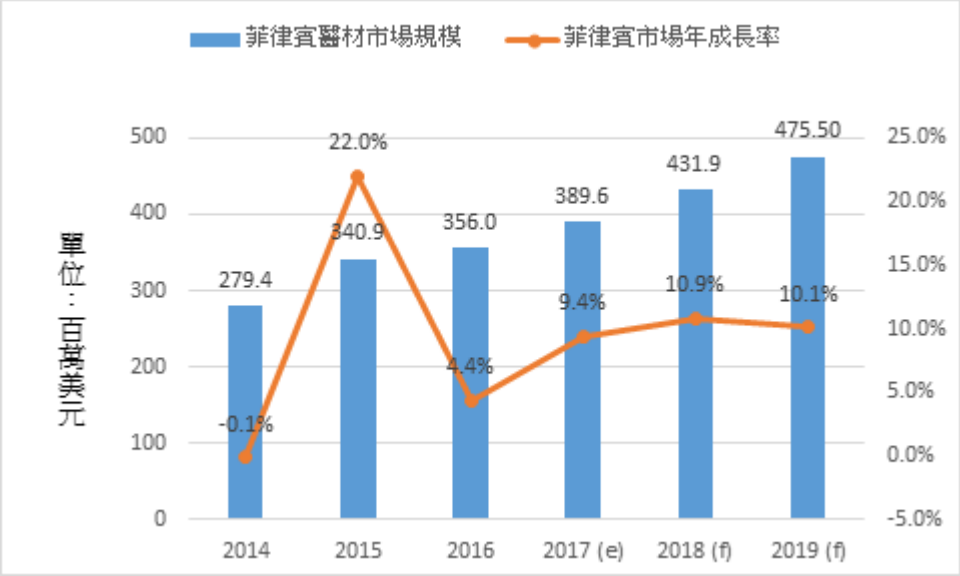
(二) 體外診斷醫療器材(In Vitro Diagnostic Medical)首次註冊文件(詳如附件 4):1. 經銷商

(進口商/出口商/批發商/本地製造商/貿易商)的公證申請表；2.品牌證明；3. 有效經銷商(進口商/出口商/批發商/本地製造商/貿易商)營業許可證；4.經過菲律賓領事館認證的產品進口許可證與自由銷售證；5. 進口品，經過菲律賓領事館認證之製造商 ISO 證書；6.最新的產品註冊證明影本；7. 國外製造商與菲律賓當地經銷商的有效的外國代理協議（Foreign Agency Agreement)；8.預期用途及使用方向；9.作為試劑/試劑盒的原料清單；10. 產品技術規格與外觀描述說明書；11.程序控制/測試程序及預期表現；12.產品生產、加工、包裝過程說明；13.風險分析與控制措施；14.產品穩定性測試報告；15.產品商標標示及標籤說明；16.產品樣本；17.繳納登記費用的證明。

貳、 菲律賓醫療器材市場

一、 依據研究機構 Espicom 的資料(如下表)，菲律賓醫療器材市場規模於 2015 年約為 3.4 億美元，2016 年成長 4.4%，規模達到 3.56 億美元。預計 2017 年至

2019 年將以年複合成長率 9%以上穩定成長，2019 年將達到 4.75 億美元。而依照菲律賓國家統計局資料，2016 年菲律賓醫療支出約為 59.79 億美元，推估醫療器材市場占菲國醫療支出之 8%。



二、 我國醫療器材有拓銷潛力

2016 我國醫療器材出口至菲國總金額約 1052 萬美元，較 2015 年 1899 萬美元下降 44.59%，主要出口項目，其他體外診斷醫療器材(609 萬美元)、眼科器具(457 萬美元)、檢驗設備(165 萬美元)、檢驗試劑(137 萬美元)。主要成長項目為: 牙科治療椅(+198.23%)、醫學影像裝置(+186.73%)、呼吸與麻醉用器具(+73.65%)、身體各部位彌補物(+39.01%)、檢驗試劑(+14.57%)。請參考 2015 及 2016 年我國醫療

器材出口至菲律賓統計表。

參、 目前菲律賓醫材公司

菲國國內醫療器材產業仍不發達，高度仰賴國外進口。菲國當地醫材領先公司為 Euro-Med Laboratories 及 Terumo。

Philippines, Inc，係一家製藥公司，公司從事製藥產品的生產，如非口服藥及其他解決方案，也製造靜脈注射液,血液透析濃縮物，眼用產品和消毒劑，Euro-Med 成立於 1988 年,目前由 U.S. Automotive Co. Inc. 持有 58.41%股權，總部設在菲律賓馬尼拉，員工 723 人，年收益 48.3 億披索。

日本 Terumo 公司則在菲律賓內湖省(Laguna Province)之 Binan City 設立注射器生產重鎮，每年產量約 17 億美元，佔該公司注射器產能 50%， 菲律賓是 Terumo 注射針筒的重要生產基地，除了回銷日本與菲律賓的本地銷售外，也透過泰國與比利時出口到東協與歐盟的其他國家。

肆、 我國廠商目前在菲律賓發展生醫產業，產品範圍包括:醫療耗材、醫療服務，知名廠商如次:

一、　邦特生技：邦特生技成立於1991年，生產及外銷洗腎之醫療耗材，菲律賓廠位於距馬尼拉約2.5小時，距Bataan自貿港區約半小時車程之Hermosa工業區，該工業區隸屬加工出口區管理署(PEZA)，享PEZA之相關免稅優惠。

二、　佳醫集團係第1家亦係目前唯一在東協開設洗腎中心之台商企業，已在大馬尼拉地區開立5家診所。另佳醫集團亦係血液透析及各種醫療器材設備、保健產品及服務之供應商，在菲銷售醫療耗材方面之排名第3，該集團近年營收約4,500萬美元，僱用員工近200人。

三、　美德向邦集團菲律賓廠：美德向邦集團創立於1988年，於1991年來菲設廠，目前營運地點包括菲律賓、台灣、中國大陸、柬埔寨及新加坡。在菲工廠5公頃，生產及外銷口罩、床單、各式醫療及軍用服裝等，從織布、染整、裁縫皆在該廠區完成，另提供本地21間醫院、近4千床位之布巾租賃洗滌整合服務，在菲員工約6百人。

伍、　建議我業者拓銷作法

一、　市場概況：由於菲國政府逐步推動全民醫療保險，期盼達成醫療保險100%全面覆蓋的政策目標，且菲律賓衛生部為因應擴大的醫療需求，提升全國20家主要醫院的硬體設施與服務程序，鑒於增加的醫療保險預算及醫療設施經費，促使菲國醫療及醫材市場擴大，簡易個人醫療及保健器材的需求增加。我國血液透析設備、血壓計、血糖機、耳溫槍、聽診器以及其他小型醫療器材等具拓銷潛力。

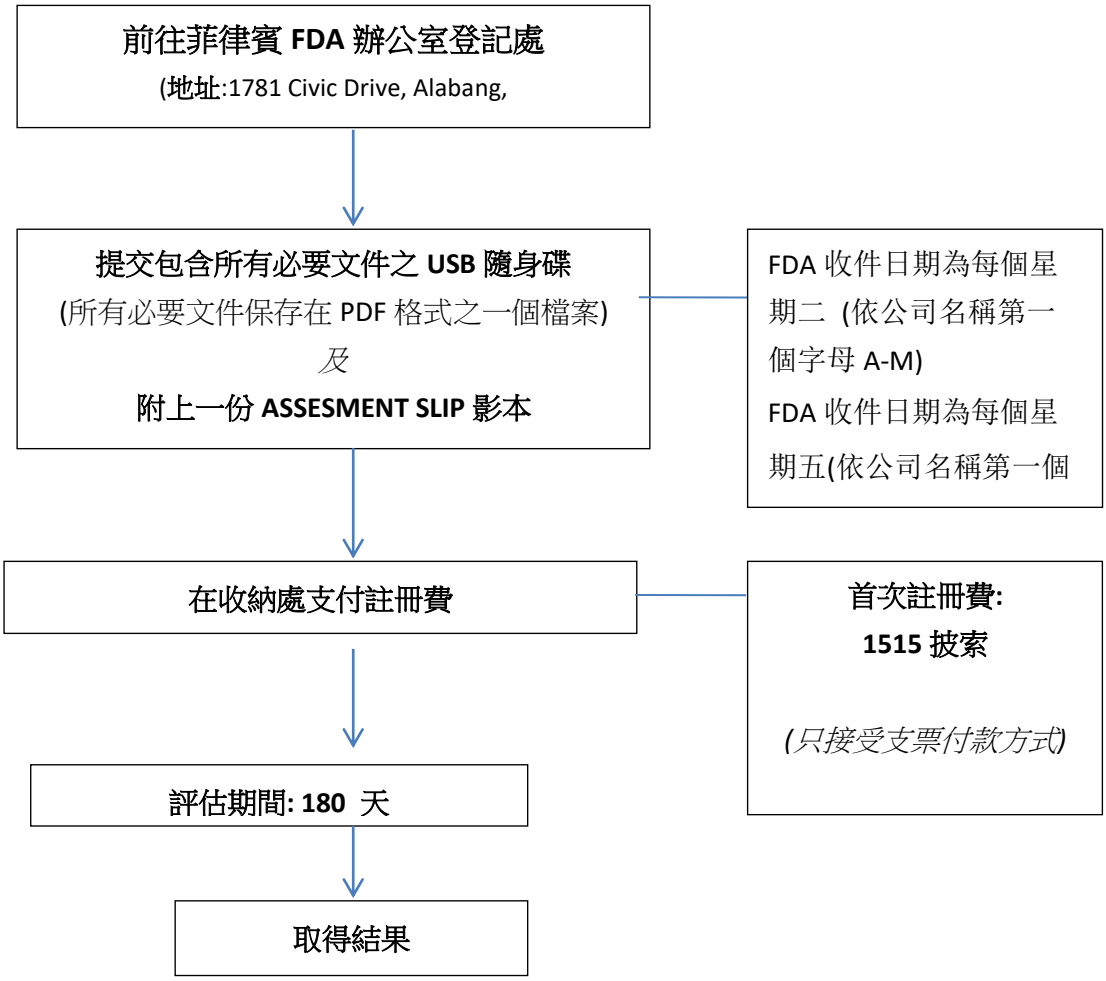
二、　深耕人脈及借重當地經銷商：對於政府部門標案，由於人為因素，獲得政府採購商機困難度高，必需長期經營建立人脈，例如此間台商美德向邦集團因與軍方關係長遠深厚，獲得穩定醫材訂單。

此外，菲國衛生部直接掌管10%公立醫院，而其餘90%的省級縣市與地區公立醫院則由各地方政府負責營運。公立醫院每年會在年底時針對明年提出需求清單，不過受到當地保護主義影響，投標仍須與當地經銷代理商合作。私立醫院因利益導向，經費充足而有能力採購精良設備，但醫院採購人員亦受限於採購其所熟悉的經銷商，因此個別醫院人脈的建立亦為成功

要素，例如此間台商佳醫集團在菲拓銷醫材成功經驗，即係深耕 20 餘年的努力結果。

有意新進入菲律賓市場者，需要尋找有聲譽的當地經銷商，借重其人脈網路進入菲律賓的醫療器材市場，此外，仍需努力提高自身產品及品牌在菲律賓的知名度，方能自德、美，日與中國大陸產品的激烈競爭中脫穎而出。

菲律賓醫材註冊程序(附表 1)



倘需更多資訊請聯繫:菲律賓 FDA 之醫材註冊中心，電話:+63.2.8211163

2015 及 2016 年我國醫療器材出口至
菲律賓統計表

單位美元

產品名稱	稅則號列	2015	2016	成長率
傷口護理器材	300510、300590	924,129	969,435	4.903
急救用品設備	300650	2,205	1,666	-24.44%
檢驗試劑	382200	1,201,899	1,377,015	14.57%
其他塑膠橡膠與紙製品	401410、401490	108,543	81,621	-24.80%
個人保護器材	401519、401590	88,288	35,189	-60.14%
行動輔助器材	660200、660390、871310、871390、871420	139199	155050	11.39%
其他體外診斷醫療器材	841869	8,588,629	6,093,099	-29.06%
眼科器具	900190、900311、900319	5,500,341	4,577,908	-16.77%
醫學影像裝置	901819	9,287	26,629	186.73%
手術與治療用醫療器材	901890	696,013	722,539	3.81%
物理治療器具	901910	149,473	123,778	-17.19%
呼吸與麻醉用器具	901920、902000	244,958	425,367	73.65%
身體各部位彌補物	902110、902139	305,993	425,353	39.01%
檢驗設備	902720、902780	1,465,850	1,657,102	13.05%
牙科治療椅	940210	9,214	27,479	198.23%
		18,992,232	10,522,844	-44.59%

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA 50

25 February 2014

FDA Memorandum Circular
No. 2014-005

TO: ALL DIRECTORS OF FDA CENTERS AND OFFICES, DOH CENTERS, BUREAUS, REGIONAL OFFICES, SERVICES, AND SPECIALTY HOSPITALS, MEDICAL CENTERS AND HOSPITALS, IMPORTERS/DISTRIBUTORS/WHOLESALERS/ RETAILERS/ MANUFACTURERS/RE-PACKERS OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC MEDICAL DEVICES, AND OTHERS CONCERNED

Subject: Updated List of Medical Devices required to be registered prior to sale, distribution and use

In pursuit of attaining systematic regulation of medical devices, including in-vitro diagnostic medical devices, the Center of Device Regulation, Radiation Health, and Research (CDRRHR) of the Food and Drug Administration, Department of Health is providing the updated list of medical devices and in-vitro diagnostic medical devices that are required for mandatory registration pending the implementation of the full regulation of all medical devices.

The list is based on the BFAD Memorandum No. 7 s. 1992 that identifies the list of registrable medical devices and from the consolidated database of registered medical devices.

The following is the initial list of medical devices and in-vitro diagnostic medical devices that are required for mandatory registration:

A. Medical Devices:

1 Abdominal Pad
2 Absorbable Hemostatic Agents
3 Abutment
4 Access/Injection port
5 Acetabular
6 Adhesive, all types
7 Administration Set, all types
8 Adaptor/Connector (all types)
9 Alcohol Swab
10 Anchor, Preformed
11 Anesthesia Set
12 Apheresis Kit

13 Artificial Saliva
14 Atopiclair Cream/Non-steroidal Cream
15 Bandage
16 Base Paste
17 Biopsy Needle/Instrument
18 Blade, all types
19 Blood Bag
20 Blood Collection Tube/Kit; Blood Sampling Tube/Kit
21 Blood Transfusion Set
22 Blunt
23 Bone Marrow Collection/transfusion Kit
24 Bone Wax
25 Breathing Circuit
26 Burette
27 Burr, Dental/Surgical/Orthopeadic
28 Cannula, all types
29 Cap (disinfection, seal, taper, dead-end)
30 Cardiotomy Reservoir
31 Catheter, all types
32 Cavity Liner
33 Cell Regeneration Kit
34 Cell Separation Kit
35 Cement, Dental/Bone
36 Central Venous Blood Pressure Kit
37 Cervical Collar
38 Cervix Set
39 Chest Drainage Kit
40 Clave
41 Clinical Thermometer, all types except mercurial
42 Clip/Clip Applier
43 Closure Device; Skin Stapler (including remover)
44 Collagen
45 Condom
46 Conical Ring Segment
47 Contact lens solution
48 Contact Lens, including cosmetic contact lenses
49 Corset Cast
50 Cotton
51 Cytology Brush
52 Delivery System
53 Dental Bone
54 Dental Restorative Material/Filler/Agent/Tooth Bonding/Etching/Varnish
55 Dental Suspension
56 Dialysate Concentrate for Hemodialysis
57 Dialyzer
58 Diamond Disc
59 Dilatation Device
60 Disinfectant of Medical Devices
61 Dissector
62 Drainage Pouche

63 Drape, Sterile
64 Dressing
65 Drill, Bone/Surgical
66 Drug Delivery Embolization System
67 Duodenal Tube
68 Ear Wax Remover
69 Earpiercing Device
70 Ecodrop - Inject
71 Electrode needle/pencil (electrosurgical)
72 Embolic Protective Device/System
73 Endoscopic Harvesting System
74 Endotracheal Tube
75 Epidural Probe
76 Evacuator
77 Extention Set/Kit
78 Feeding Set
79 Filler
80 Filter
81 Filtration Device
82 Flowmeter, blood, cardiovascular
83 Former Compact
84 Gastric Band
85 Gauze
86 Gingiva Former
87 Gloves (surgical, examining, sterile, non-sterile)
88 Graft, bone/skin/vascular/biological
89 Guidewire, guide catheter
90 Heart Valve
91 Heart Valve/Annuloplasty Ring
92 Hemoconcentrator
93 Implantable Defibrillator
94 Implantable hearing device
95 Implantable Lead
96 Implantable Pacemakers
97 Implantable Prosthesis
98 Impression Material
99 Inflation Device
100 Infusion Fluid Thermal Warmer
101 Infusion System
102 Injectors
103 Intraocular Lens
104 Introducer Kit
105 IUD
106 IV Container
107 Knife, all types, sterile
108 Knot Pusher
109 Lancet
110 Laryngeal mask
111 Ligating Clip
112 Light Shield

113 Lubricating Gel/Jelly
114 Luer lock
115 Lumbar Puncture Tray
116 Manual Resuscitator with Mask
117 Mask (facemask, full mask, anesthesia, oxygen)
118 Moisture/Lubricating Eyedrop
119 Nasal Spray
120 Nasopharyngeal Airway
121 Nebulizing Kit with mask
122 Needle (all types) except for tattoo and acupuncture
123 Neurovascular Remodelling Device
124 Neurovascular/Endovascular Coil
125 Ophthalmic Drop/Solution
126 Ophthalmic Viscoelastic Device
127 Orthopeadic Implants (all kinds)
128 Orthopeadic Wire
129 Peak Flowmeter
130 Percutaneous Retrieval Device
131 Plaster of Paris
132 Plaster, all types
133 Plastic Strip
134 Plumset
135 Reconstruction Kit/Device; Fixation Device
136 Renal Dilatation Set
137 Revascularization Device
138 Root Canal Sealing Material
139 Rotahaler
140 Scalp Vein Infusion Set
141 Skin Retractor
142 Scrub, w/o drugs
143 Sealant
144 Self Adhering Wrap
145 Shunt System
146 Silicon Oil in Vial for Ophthalmic Use
147 Skin Barrier for Ostomy Use
148 Skin Traction Set
149 Sodium Hyaluronate
150 Spinal Anaesthesia Tray
151 Spine System
152 Stent
153 Sterilant for medical device
154 Stoma Adhesive Protective Powder/wafer
155 Stoma Bag
156 Stop-cock
157 Suction, Airway Kit
158 Surgical Mesh
159 Surgical Milk
160 Surgical Pack/Surgical Kit
161 Suture (with or without needle)
162 Suture Anchor

163	Synthetic Cast Padding
164	Syringe (with or without needle)
165	Tape, surgical/medical
166	Thrombectomy Set
167	Tissue Expander
168	Tissue Measuring Device
169	Tracheostomy Kit
170	Transfer Pack
171	Trocar System
172	Tube, all kinds that are connected to the patient or will be used to pass any type of fluids going into or from the patient's body)
173	Tulle Dressing (without drugs/medicine)
174	Umbilical Clamp
175	Urine Collecting Bag
176	Varnish, Cavity
177	Vascular Access System
178	Ventricular Probe
179	Wound Drainage Kit
180	All other implantable medical devices (in parts or in system)

B. In-Vitro Diagnostic (IVD) Medical Devices:

1. HIV (antibody and/or antigen), HBV (HBsAg and other markers), HCV (antibody and/or antigen) and syphilis (Treponemal and non-treponemal) kits for:
   - Screening Test
   - Confirmatory Test
   - Other marks for nucleic application systems for in-vitro diagnostic use and test to monitor disease activity (e.g. iral load test, other serologic markers for Hepatitis B)
2. Single or combination drug screening test kits/reagents for THC/marijuana, Shabu/MET, Cocaine, Benzodiazepine, Ecstacy/MDMA and Opiates/Morphine
3. Blood Typing Sera for Anti-A, Anti-B, Anti-D, Anti-AB
4. Anti-human Globulin Reagents
5. Potentiators such as enzyme, LISS and albumin
6. Column Agglutination test for crossmatching & blood typing
7. Pregnancy test kits/reagents
8. Leptospirosis test kits/reagents

All medical devices that have any of the abovementioned devices in part or in whole shall be considered registrable.

Application shall be made separately per specific medical device. In case of the following conditions, only one application can be filed; however, separate product certification/s shall be issued:

- medical device with accessories that are intended to be sold separately;
- medical device manufactured in multiple manufacturing sites and shall co-exist in the market;
- medical device system where the use of one part of the system is needed to be used together with all or any part of the system;
- medical devices with the same intended use and the same manufacturing process but differ in one or more raw materials;
- medical devices with the same intended use and the same manufacturing process but differ in the design;
- medical devices with the same raw materials but differ in types or shapes resulting in different specific intended uses.

The registration fee for this type of application shall be equivalent to the total registration fee for all the individual products that will be registered.

All unregistered medical devices included in this Memorandum Circular that are not listed in BFAD Memorandum Circular No. 7 s. 1992 shall be given one year from the time this Circular is approved to file the application for registration; otherwise, all unregistered medical devices included in this list shall not be allowed to be sold and distributed and corresponding sanctions based on Republic Act 9711 shall be imposed.

All devices indicated in the list are used in medical application. Other devices that are similar in terminology but are NOT for medical use shall not be considered as medical devices.

Medical devices that were issued with a CPR that are not included in this list will remain as registrable devices and should inform the CDRRHR-FDA.

This FDA Memorandum Circular shall supersede BFAD Memorandum Circular No. 7 s. 1992.

This Memorandum Circular shall take effect immediately.

KENNETH HARTIGAN-GO, MD
Acting Director-General

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 June 2015

FDA MEMORANDUM CIRCULAR
No. 2014 - 005-A

SUBJECT: **Amendment to FDA Memorandum Circular No. 2014-005, "Updated List of Medical Devices Required to be Registered Prior to Sale, Distribution and Use"**

To clarify the list of medical devices required to be registered, the FDA Memorandum No. 2014-005 is hereby amended as follows:

Item No.	From	To
14	Atopiclair Cream/Non-steroidal cream	Non-steroidal cream for skin barrier repair
18	Blade	Surgical Blade
22	Blunt	Delete in the list
40	Clave	Delete in the list
53	Dental Bone	Dental Bone Implant
63	Drape, Sterile	Surgical Drape, Sterile
65	Drill, Bone/Surgical	Drill Bit, Bone/Surgical
107	Knife, all types, sterile	Surgical Knife, sterile
112	Light Shield	Eye Light Shield
115	Lumbar Puncture Tray	Lumbar Puncture Kit
117	Mask (facemask, full mask, anesthesia, oxygen)	Mask (facemask, full mask, anesthesia, oxygen). Exempted from registration: N95, washable, earloop facemask.
142	Scrub, w/o drugs	Surgical Scrub, w/o drug component
150	Spinal Anaesthesia Tray	Spinal Anaesthesia Kit

All other provisions of FDA Memorandum No. 2014-005 shall remain in effect.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General, Food and Drug Administration

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

Food and Drug Administration PHILIPPINES

QWP-CDRRHR/LRD-02 Annex 02
Rev. No. 04

CHECKLIST OF REQUIREMENTS FOR CERTIFICATE OF PRODUCT REGISTRATION OF MEDICAL DEVICES

1.	Table of Contents (with page number)
2.	Notarized Application Form from Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader
3.	Valid License to Operate (LTO) of Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader
4.	Valid Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product
5.	Valid Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities or valid ISO Certification for Imported Product. For imported products, certificate must be and duly authenticated by the territorial Philippine Consulate
6.	Valid Certificate of Foreign Agency Agreement between the manufacturer and trader / distributor / importer regarding the product involved duly authenticated by the territorial Philippine Consulate
7.	Specific Use and Directions/Instruction for use
8.	List of all raw materials used as component of the product. Must include quantity and technical specifications or detailed information on physical and chemical properties of each component
9.	Brief description of the methods used, the facilities and control in the manufacture, processing, and packaging of the product. For sterile products, include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation with sterility tests. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company.
10.	Technical specifications and physical description of the Finished Product. Submit also the following: (a) Functionality/performance test data and results conducted on the finished product; (b) Test data and results of the Biocompatibility test of the device being registered; (c) Risk analysis with control measures, if applicable
11.	Stability study of the product duly signed by the person who conducted the studies to justify claimed expiration date. For accelerated study, submit computation to justify the storage condition used. If no expiration, submit justification from the manufacturer why the device has no expiration.
12.	Labeling materials for all the sizes/reference codes to be used for the product: Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable
13.	Representative sample (as needed) and clear colored photo of the actual commercial product sample without its packaging
14.	Evidence of registration fee/payment (charge slip/official receipt)

- *Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi)*
- *The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.*
- *Bring hard copy of the assessment slip*

CHECKLIST OF REQUIREMENTS FOR THE REGISTRATION OF AN IN VITRO DIAGNOSTIC DEVICES

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Table of Contents (with page number)	√	√
2. Notarized Application Form from Distributor (Importer/Exporter/Wholesaler)/Local Manufacturer/Trader	√	√
3. Certificate of Brand Name Clearance (for branded products, if applicable)	√	
4. Valid License to Operate (LTO) of an IVD Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader	√	√
5. Valid Government Certificate of Clearance and Free Sale/Registration approval of the Product from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	√	
6. Valid Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities or valid ISO Certification for Imported Product. For imported products, certificate must be and duly authenticated by the territorial Philippine Consulate	√	√
7. Copy of latest Certificate of Product Registration	N/A	√
8. Certificate of Foreign Agency Agreement between the manufacturer and trader/distributor/importer regarding the product involved duly authenticated by the territorial Philippine Consulate	√	√
9. Intended use and Directions for Use	√	
10. List of all raw materials used as components of the reagents/test kit	√	
11. Technical specifications and physical description of the Finished Product	√	
12. Process-control/Test Procedure and expected performance specification	√	
13. Brief description of the methods used in the facility and the controls in the manufacture, processing, packaging of the IVD and the process flowchart showing an overview of production	√	
14. Risk analysis with control measures	√	
15. A. For INITIAL: Stability test data and results describing the shelf life, in-use stability, and the shipping stability studies to justify claimed shelf life. The testing should be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions. B. For RENEWAL: Stability test data and results describing the shelf life. The testing should be performed on at least three (3) different product lots manufactured under **REAL TIME CONDITION**.	√	√
16. A. For INITIAL: Labeling materials to be used for the product: Immediate label, secondary packaging, box label and package insert/brochure. B. For renewal, submit clear and readable commercial product label specimen of all labeling materials (outer, immediate, package insert)	√	√
17. Representative sample in the market or commercial presentation (15 kits for pregnancy tests) (2 samples for drug screening test kits)	√	√
18. Evidence of registration fee/payment (charge slip/official receipt)	√	√

- *Application should be filed six (6) months prior to the expiration of the validity of the CPR.*
- *Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi).*
- *The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.*

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

QWP-CDRRHR/LRD-03 Annex 01
Rev. No. 04

- *Bring hard copy of the assessment slip.*