MEDICAL DEVICE - DRUG - COSMETIC INTERPHASE (MDDCI) PRODUCTS

1. INTRODUCTION

a) Medical Device-Drug-Cosmetic Interphase (MDDCI) Products are those products that are not clearly defined as a medical device or drug/cosmetic in accordance to the Medical Device Act 737, Control of Drugs and Cosmetics Regulations 1984 and Sale of Drugs Act 1952.

b) Registration of drug products/ notification of cosmetics that has been classified must follow the requirements that have been set forth as follows:

   i. **Drugs & Cosmetics** – The registration/ notification regulated by the NPRA is in accordance with the requirements set forth in the Poisons Act 1952 and its Regulations, Sales of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984;

   ii. **Medical Device** – The registration regulated by Medical Device Authority is in accordance with the requirements set forth in the Medical Devices Act 2012 (Act 737).

c) Combination products includes:
   i. A product comprised of two or more regulated components, i.e., drug/device, biological/device, or drug/device/biological, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
   ii. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products.

d) For Interphase Product and Combination Product (Device-Drug or Drug-Device), it will be regulated according to the classification that has been made and by the relevant agencies.

e) Please refer to:
   i. Directive No. 4 Year 2017, Ref. (9) dlm.BPFK/PPP/07/25 Jld. 1 : Direktif Kuatkuasa Pemakaian *Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products*
   ii. Guideline For Registration Of Drug-Medical Device and Medical Device-Drug Combination Products

2. CLASSIFICATION CRITERIA

a) The following may be used as criteria to assist in the classification of products:

i. The primary intended purpose of the product;

ii. The primary mode of action/ the principal mechanism of action by which the claimed effect or purpose of the product is achieved;

- Drug is based on pharmacological, immunological or metabolic action in/on the body; but
- Medical device does not achieve its primary mode of action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means;

iii. Active ingredient, indication and pharmaceutical dosage form (these are the main criteria for classification of the drugs);

iv. Classification of the products in reference countries.

b) For classification of MDDCI products and combination products as decided by the committee, please refer to **Table I**. It shall be used as guidance for classification only.

c) Applicant shall verify on MDDCI product classification with NPRA in order to determine whether the product shall be registered by the Authority or otherwise.

Table I: MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
1.	**Aqueous Cream Product**	As an emollient cream with moisturizing properties to promote healing and relief to the symptoms of skin dryness, impaired barrier function, skin problems/ diseases.	**OTC DRUG**	**NPRA**
2.	**Blood bag containing anticoagulant/ preservation agent**	To collect and preserve blood and its components (for use with cytapheresis device only) **NOTE :** It is not for direct intravenous infusion.	**MEDICAL DEVICE**	**MDA**
3.	**Catheter Lock/ Flush Solutions** (eg. heparinised saline, sodium citrate solution)	As an anticoagulant for use as a catheter lock / flush solution for flushing off catheters and cannulas to maintain catheter/ cannula patency and to prevent coagulation of blood or infection in the catheter. **NOTE :** - It is not indicated for therapeutic use. - Contraindicated for direct systemic administration.	**MEDICAL DEVICE**	**MDA**
4.	**Collagen Hemostatic Agents** (fibrillar or soft, pliable pad/sponge or loose fibres)	A sterile, bioabsorbable device derived from animal collagen (e.g., bovine or porcine collagen) designed to produce a rapid haemostasis through platelet	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		activation/aggregation (which initiates the haemostatic cascade leading to a fibrin clot) during a surgical procedure. It is applied directly to the wound where it remains to be absorbed by the body; it is not dedicated to a specific anatomy/application and does not contain an antimicrobial agent.		
5.	**<u>Dental Products</u>**			
	i. Fluoride dental preparations (eg. toothpaste, tooth powder, mouthwash, dental varnish/ suspension)	a. To maintain oral hygiene.	**COSMETIC** (If concentration of fluoride ≤ 1500ppm)	**NPRA**
		b. To maintain oral hygiene and prevent oral diseases based on pharmacological, immunological or metabolic action	**DRUG**	**NPRA**
		c. A liquid substance used for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations. A thin coating of this solution is applied over the tooth's surfaces before placement of restorations. It is used as a protective agent for the tooth against constituents of restorative materials. After application, this device cannot be reused.	**MEDICAL DEVICE**	**MDA**
		d. As a desensitizing agent for the treatment of hypersensitive teeth, for sealing the dentinal	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		tubules for cavity preparations or on sensitive root surfaces or to line cavity preparations under amalgam restorations.		
	ii. Root canal filling incorporating antibiotic	To seal the canal and disinfect the dentinal walls by diffusing through dentine. The antibiotic provides ancillary actions as bactericidal antibiotic and anti-inflammatory agent to assist in reducing pain and in maintaining a bacteria-free environment within the root canal.	**Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**
	iii. Oral wound dressing, non - animal/ microbial derived (e.g., gel, paste, fluid, spray solution of water/oil).	A compound intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It may also be used to treat mucosal irritations/ inflammation, dryness and gingivitis.	**MEDICAL DEVICE** (If it contains an active substance with pharmacological, immunological or metabolic primary mode of action, it will be classified as **DRUG**)	**MDA**
6.	**<u>Dialysis Products</u>**			
	i. Peritoneal dialysis dialysate	It is used for the exchange of solutes across the peritoneum of the patient (in this case, used as a semi-permeable membrane)	**DRUG** For continuous ambulatory peritoneal dialysis (CAPD) products with CAPD system (eg dialysate bag, drainage	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
			bag, transfer tubing, linking connector, disc, injection port, overpouch etc), it will be classified as **Drug-device combination product regulated as DRUG** **(refer to No.9. <u>Drug - Delivery Products Regulated as Drug Products</u>)**	
	ii. Haemofiltration solution	It is used for the exchange of solutes with blood through a system of extracorporeal filters.	**DRUG**	**NPRA**
	iii. Haemodialysis dialysate	It is used for the exchange of solutes with blood through a semi-permeable membrane in the dialyser of a haemodialysis system.	**MEDICAL DEVICE**	**MDA**
	iv. Haemodiafiltration solution	It is used as a replacement solution in haemodiafiltration. **NOTE** : Haemodiafiltration is the combination of haemodialysis and haemofiltration performed either simultaneously or sequentially.	**DRUG**	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
7.	**<u>Drug-Eluting Beads</u>** (Produced from biocompatible polyvinyl alcohol hydrogel modified with sulphonate groups in phosphate buffered saline.)	It is an embolic agent which is intended to be loaded with a chemotherapy agent, eg. doxorubicin for the purpose of treatment of malignant hypervascularised tumour(s) by embolisation of vessels and occlusion of blood flow supplying malignant hypervascularised tumour(s) and as a secondary action, delivers/elutes a local, controlled, sustained dose of the chemotherapy agent directly to the tumour(s).	If the beads are sold separately from the drug, it will be classified as **MEDICAL DEVICE** If the beads and drug are packaged and sold together, it will be classified as **Drug-device combination product regulated as DRUG**	**MDA/NPRA**
8.	**<u>Drug-Eluting Stents (DES)</u>**	For use in angioplasty or coronary stenting procedures.	**Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**
9.	**<u>Drug - Delivery Products Regulated as Drug Products</u>** (eg. insulin prefilled pen/ syringes, asthma inhalers, intrauterine with hormone action CAPD products with CAPD system (eg. dialysate bag, drainage bag, transfer tubing, linking connector, disc, injection port, overpouch etc)	To administer pharmacologically active substance	**Drug-device combination product regulated as DRUG**	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
10.	**<u>Enteral Feeding Kit</u>** (containing Iodine Pack drug)	A collection of sterile devices that includes tubing and other materials intended to administer nutrient liquids directly into the stomach, duodenum, or jejunum of a patient by means of gravity or an enteral pump.	**Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**
11.	**<u>Eye Products</u>**			
	i. Eye/ ocular lubricants, including artificial tears	A sterile substance used to provide supplemental lubrication/hydration/ moisturization to the eyes to treat/ alleviate symptoms of soreness, burning, irritation and discomfort caused by dry, tired, and/or strained eyes resulting from dry eye syndrome, ageing/ hormone changes (menopause), or environmental factors (e.g., pollution, dust, heat, smoke and air conditioning).	**MEDICAL DEVICE** (If it contains an active substance with pharmacological, immunological or metabolic primary mode of action, it will be classified as **DRUG**)	**MDA**
	ii. Aqueous/vitreous humour replacement medium	It is used to assist in performing ophthalmic surgery, e.g., to maintain the shape of the eyeball during the intervention, preserve tissue integrity, protect from surgical trauma, or to function as a tamponade during retinal reattachment.	**MEDICAL DEVICE**	**MDA**
	iii. Cold Sensation Eye Pillow	To reduce fatigue from work stress or lack of sleep.	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
12.	**General Purpose Surgical or Barrier Drapes** (A sterile protective covering made of natural or synthetic materials, or both.)	To isolate a site of surgical incision or a surgical field from contamination (e.g., microbial, substance) in various clinical settings (e.g., in an operating room or catheterization laboratory). The device may also be used to protect a patient from heat/flame during a surgical procedure. This is a reusable or single use device.	**MEDICAL DEVICE** (If it incorporates an ancillary pharmacologically active substance, it will be classified as **Device-Drug combination product regulated as MEDICAL DEVICE)**	**MDA**
13.	**General-body orifice lubricant**	Lubricant intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and the body; Lubricant during catherisation, probing,endoscopy, changing fistula catheters,intubation,and prevention of iatrogenic injuries to the rectum and colon. E.g ancillary local anaesthetic: lidocaine	**MEDICAL DEVICE** (If it incorporates an ancillary pharmacologically active substance, it will be classified as **Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**
14.	**Head lice products**	a. Acts solely by coating and/ or suffocating the lice and/ or its eggs	**MEDICAL DEVICE**	**MDA**
		b. Disrupting the water balance mechanism of the lice by dissolving and emulsifying off their protective cuticular lipid layer, alters physical	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		characteristics of the egg so that the mymph develops to maturity but cannot hatch.		
		c. To coat the hair in a film that deters lice from transferring from an infected head to the one treated	**MEDICAL DEVICE**	**MDA**
15.	**<u>Heat Pad/ Cooling Pad</u>**	To relief aches and pains.	**MEDICAL DEVICE**	**MDA**
16.	**<u>In vivo diagnostic agents</u>**	a. Topical/ intraocular/ intravitreal ophthalmic staining agents for diagnostic, enhance visualisation during ophthalmic procedures and/or contact lense fitting; such as fluorescein ophthalmic strips, trypan blue, brilliant blue, methylene blue.	**MEDICAL DEVICE**	**MDA**
		b. For diagnostic purposes, other than No. 16(a) such as: - Intravenous Fluorescein dye for ophthalmic angiography, e.g. Fluorescein injection - X-ray / MRI contrast media - NMR enhancing agents - Carrier solutions to stabilize microbubbles for ultrasound imaging - Radiopharmaceuticals for diagnostic use eg 14C- Urea Capsule for H pylori test	**DRUG**	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		- Hapten preparation for the diagnosis of contact allergy		
		c. As Diagnostic Test Kit consist of drug and analyser	**DRUG**	**NPRA**
		d. As diagnostic analyser only (without drug)	**MEDICAL DEVICE**	**MDA**
17.	**<u>Irrigation solutions</u>**	For mechanical cleansing and rinsing including those used in the eye such as for cleansing of the eye, body tissues, body cavities, wounds or irrigation of a special tube called a catheter which is used to drain the bladder.	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it will be classified as **DRUG**)	**MDA**
18.	**<u>Local refrigeration anaesthesia</u>**	Used as local anaesthetic due to intense cold produced by instant evaporation e.g. in minor operative procedures or to alleviate pain associated muscle injuries etc; of which results in insensitivity of peripheral nerve endings and a local anesthesia. Its principal mode of action is not is not pharmacological, immunological or metabolic	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it will be classified as **DRUG**)	**MDA**
19.	**<u>Medicinal gases</u>**	a. Gases or gas mixtures which mode of action is achieved primarily based on pharmacological, immunological or metabolic action in/on the body, such as gases for hypoxia (oxygen gas) and anaesthetic (nitrous	**DRUG**	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		oxide gas)		
		b. Gases or gas mixtures which mode of action is achieved primarily by physical in nature and not achieved primarily based on pharmacological, immunological or metabolic action in/on the body, such as gases for insufflation of the abdominal cavity for laparoscopy and gases for removal of warts (e.g., liquid nitrogen).	**MEDICAL DEVICE**	**MDA**
20.	**<u>Medicinal Patch</u>**	To relieve fatigue, body aches, joint pains; To regulate hormone imbalance	**DRUG**	**NPRA**
21.	**<u>Nail Anti-fungal Products</u>** (eg. pen applicator containing acetic acid/ lactic acid)	Treatment of onychomycosis (fungal nail infection) by lowering the pH of the nail bed, thus creating a micro-environment that is hostile to fungal growth.	**MEDICAL DEVICE**	**MDA**
22.	**<u>Nasal inhaler/ spray</u>**	To act as a barrier against external influences by formation of a moisturizing film on the nasal mucosa.	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it will be classified as **DRUG**)	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
23.	**<u>Oral care products</u>**			
	Artificial Saliva / Saliva Substitute/ Replacement (eg. rinses, sprays, swabs, gels, tablets that dissolve in mouth)	Solutions used to mimic and replace/substitute normal saliva in the symptomatic treatment of dry mouth (xerostomia). Generally, contain viscosity-increasing agents, such as mucins or cellulose derivatives such as carmellose as well as electrolytes, including fluoride. They seldom relieve symptoms for more than 1 or 2 hours and does not stimulate saliva production.	**MEDICAL DEVICE**	**MDA**
24.	**<u>Other topical antiseptics/ disinfectants</u>**			
	i. Swabs/ Wipes containing antiseptics/ disinfectants/ antimicrobial substances (eg. chlorhexidine, iodine, cetrimide)	For use on human skin and intended to be used for a medical purpose, eg pre/post injection, wound cleaning etc.	**DRUG**	**NPRA**
	ii. Preparations (including swabs/ wipes) containing antiseptics/ disinfectants/ antimicrobial substances (eg. alcohol, chlorhexidine, iodine, cetrimide)	Intended for the disinfection of medical devices.	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
	iii. Alcohol wipes/ swab	To be used for a medical purpose to wipe intact skin for needles access.	**MEDICAL DEVICE**	**MDA**
25.	**<u>Peeling/Exfoliator Products</u>** (eg. Products containing glycolic acid and salicylic acid)	To improve skin texture due to unaesthetic skin appearance caused by pigmentation, post acne scars, photo damage, etc. **NOTE :** The ingredient and intended use should comply with the Guidelines for Control of Cosmetic Products in Malaysia.	**COSMETIC**	**NPRA**
26.	**<u>Personal Care Products</u>**			
	i. Personal Intimate Hygiene	a. For female/male intimate hygiene **NOTE** : The product should be rinsed off.	**COSMETIC**	**NPRA**
		b. For symptomatic relief of vaginal irritation/ infections: i. changing the vaginal pH by physical means	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it may be classified as **DRUG**)	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
	ii. Vaginal Douche	Vaginal douching is the process of intravaginal cleansing with a liquid solution for : - personal hygiene or aesthetic reasons - preventing or treating/managing vaginal infections - symptomatic relief of minor vaginal soreness, irritation, itching - cleansing and deodorizing after menstruation - washing out vaginal medication, if so instructed by the physician - deodorizing and washing out the accumulations of normal secretions - removing contraceptive creams and jellies - cleansing the vaginal vault after sexual relations **NOTE :** - Douching is not recommended during pregnancy - A douch is to be used as a cleanser and it should not be used as a contraceptive	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it may be classified as **DRUG**)	**MDA**
	iii. Hand sanitizer (eg. gel, foam, liquid)	For general hand hygiene without therapeutic claims.	**COSMETIC**	**NPRA**
	iv. Personal Intimate	To use as a vaginal lubricant during the climaterium	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
	Lubricant	(pre-menopause, menopause, post-menopause) and to treat irritations in vaginal epithelium in cases of physiological decrease of lubrication and consequent increase in vaginal dryness.	(If it contains a pharmacologically active substance, it may be classified as **DRUG**)	
27.	**Skin Barrier Product** (eg. lotion, emulsion, ointment, cream)	a. To form a physical barrier between the skin and the environment to seal out moisture in order to promote healing and relief to the symptoms of skin dryness, impaired barrier function, skin problems/ diseases.	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it may be classified as **DRUG**)	**MDA**
		b. Soothe and prevent diaper rash discomfort.	**DRUG**	**NPRA**
		c. To maintain/ improve normal skin condition without any therapeutic claims.	**COSMETIC**	**NPRA**
28.	**Soft tissue filler/ Dermal filler**	To correct cutaneous contour deformities of the skin (e.g., moderate to severe facial wrinkles and folds such as nasolabial folds, scars), particularly in cases of aging or degenerative lesions.	**MEDICAL DEVICE** (If it incorporates an ancillary local anaesthetic eg. lidocaine, it will be classified as a **Device-Drug combination product regulated as**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
			MEDICAL DEVICE)	
29.	**<u>Synthetic fluid tissue reconstructive material</u>**	As a submucosal implant in the urinary tract for urinary incontinence or vesicoureteral reflux. It may also be injected into the vocal cords to treat the effects of paralysis, atrophy, or scarring. After application, this device cannot be reused.	**MEDICAL DEVICE** (If it incorporates an ancillary pharmacologically active substance eg. local anaesthetic such as lidocaine, it will be classified as a **Device-Drug combination product regulated as MEDICAL DEVICE)**	
30.	**<u>Product for Synovial joint</u>**	a. Used as synovial fluid replacements where viscosupplementation provides support and lubrication to help cushion the joint, especially in cases of reduced endogenous synovial fluid viscosity from degenerative disease.	**MEDICAL DEVICE**	**MDA**
		b. Elicits pain relief and improvement in osteoarthritis via several complex biochemical actions resulting modulation of cell activity	**DRUG**	**NPRA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
31.	**<u>Wart Products</u>** (eg. pen applicator containing a caustic agent, cyryogenic kit with refrigerant)	a. Containing a caustic agent eg. trichloroacetic acid (TCA) that destroys warts by chemical coagulation of proteins.	**DRUG** **NOTE :** If there a device component is present, it will be regulated on a case to case basis	**NPRA**
		b. Cryotherapy which destroys warts by freezing them using a very cold substance eg. liquid nitrogen or refrigerant made from dimethyl ether and propane.	**MEDICAL DEVICE**	**MDA**
32.	**<u>Wound care/ treatment products</u>**			
	i. Comprising a matrix (eg. dressing, gauze, swabstick, plaster, sponge)	a. To administer a medicinal substance to the wound eg. antimicrobial/ antiseptic agent for the purpose of controlling infection**.**	**DRUG**	**NPRA**
		b. To provide a protective layer/barrier to the wound and prevent microbial penetration and create healing environment. It may incorporate an ancillary medicinal substance eg. antimicrobial/ antiseptic agent.	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
	ii. Comprising a matrix, typically of living cells (fibroblasts) and/or structural proteins	To facilitate the infiltration of native skin elements (e.g. fibroblasts, leukocytes, blood vessels) for skin regeneration.	**MEDICAL DEVICE**	**MDA**
	iii. Topical preparation for application to a skin wound (e.g., abrasion, laceration, cut, ulcer)	To facilitate local haemostasis. It is available in various forms (e.g., gel, spray, powder, ointment, plaster/gauze pad) that can be applied directly to the wound where it forms a seal of transparent layer.	**MEDICAL DEVICE**	**MDA**
	iv. Deep cavity wounds dressing for application to a surgical wound	To use as the wound covering material for deep body cavity to reduce the adhesion of surrounding tissues by applying to the surgical area.	**MEDICAL DEVICE**	**MDA**
	v. Silver-containing topical preparations for application to a skin wound	a. To administer/ apply an antiseptic/ antimicrobial to wounds for the purpose of treating infection	**DRUG**	**NPRA**
		b. Treatment of wounds by creating a viscoelastic and lubricated environment and providing a protective barrier at the level of the lesion, for natural wound healing, of which the silver acts as	**MEDICAL DEVICE**	**MDA**

NO	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN AGENCY
		ancillary medicinal substance		
	vi. Intravascular catheter securement device containing antimicrobial/antiseptic agent (e.g. chlorohexidine gluconate, CHG)	An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin. The antimicrobial agent provides ancillary antimicrobial activity to reduce skin colonization and catheter colonization, suppress regrowth of microorganism's, and reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	**DEVICE-DRUG combination product regulated as MEDICAL DEVICE**	**MDA**

Note:

- The above table is to be used as guidance for classification only.
- The registration/notification of products that have been classified must follow the requirements that have been set forth as follows:

i- **Drug & Cosmetic** – The registration/notification is in accordance with the requirements set forth in the Poisons Act 1952 and its Regulations, Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984.

ii- **Medical Device** – The registration is in accordance with the requirements set forth in the Medical Devices Act 2012 (Act 737).

- **Medical Device** will be regulated by **MEDICAL DEVICE Authority.**

- **Drug & Cosmetic** will be regulated by the **NATIONAL PHARMACEUTICAL REGULATORY AGENCY, Ministry of Health Malaysia.**
- **Drug – Device Combination Product** will be regulated according to the classification that has been made and by the relevant agencies.

  (Reference Circular : Bil (21) dlm.BPFK/PPP/01/03 Jld. 3)

GUIDANCE FOR THE CLASSIFICATION OF MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) PRODUCTS