APPENDIX 2

MEDICAL DEVICE - DRUG - COSMETIC INTERPHASE (MDDCI) AND COMBINATION PRODUCTS

IMPORTANT NOTES:

This document shall be read in conjunction with the relevant sections of the main guidance document: **Drug Registration Guidance Document (DRGD),** which is in accordance to the legal requirements of the **Sale of Drugs Act 1952** and the **Control of Drugs and Cosmetics Regulations 1984.**

1. INTRODUCTION

a) Medical Device-Drug-Cosmetic Interphase (MDDCI) products are products not clearly defined as a medical device, drug or cosmetic in accordance with the Medical Device Act 737, Control of Drugs and Cosmetics Regulations 1984 and Sale of Drugs Act 1952. It is important to determine whether the products are regulated as medical device, drug or cosmetic because different regulatory requirements apply.

b) Combination products include:

i. A product comprising 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; OR

ii. Two or more separate products packaged together (co-packaged) in a single package or as a unit and comprised of drug and device products, device and biological products.

c) Products that are excluded from the term "combination product" and will be regulated separately:

i. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labelling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product labelling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

ii. Any investigational drug or device packaged separately that according to its proposed labelling is use only with another individually specified investigational drug, device or cosmetic product where both are required to achieve the intended use, indication or effect.

iii. Convenience pack product (e.g., first aid kit consists of medical device and non-scheduled poison product)

iv. Natural products and Health Supplement products

d) MDDCI and Combination Products (Device-Drug or Drug-Device) will be regulated by the relevant agencies according to the classification that has been made.

e) The registration of drug/ medical device and notification of cosmetics that have been classified must follow the requirements that have been set forth as follows:

i. **Drugs and Cosmetics** – The registration / notification regulated by the NPRA 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 regulated by Medical Device Authority is in accordance with the requirements set forth in the Medical Device Act 2012 (Act 737).

f) Please also refer to:

(i) Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products

(ii) *Bil. (6) dlm.BPFK/PPP/01/03Jld.4*
Pekeliling Keperluan Acknowledgement Receipt/ Endorsement Letter *bagi Pendaftaran Baru/ Pendaftaran Semula Produk Kombinasi Ubat-Peranti Perubatan* (Drug-Medical Device Combination) (11 October 2019)

(iii) *Bil. (3) dlm.BPFK/PPP/01/03Jld.4*
Pekeliling Lanjutan Tarikh Pelaksanaan Pemakaian Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products (22 December 2017)

(iv) *Bil. (9) dlm.BPFK/PPP/07/25 Jld.1*
Direktif Kuatkuasa Pemakaian Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products (10 March 2017)

(v) *Bil. (21) dlm.BPFK/PPP/01/03Jld.3*
Pekeliling Mengenai Pengkelasan Semula Produk-produk Daripada Kategori Ubat (Drug) *Kepada Kategori Peranti Perubatan* (Medical Device) (9 December 2014)

2. CLASSIFICATION CRITERIA

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

a) The primary intended purpose of the product;

b) 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 intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means;

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

d) Classification of the product in reference countries.

For classification of MDDCI and Combination Products refer to **Table I**.

Applicant may verify the product classification with NPRA to determine if the product shall be registered with the Authority or otherwise.

Table I: MEDICAL DEVICE-DRUG-COSMETIC INTERPHASE (MDDCI) AND COMBINATION PRODUCTS CLASSIFICATION DECISION

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
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** (e.g. 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**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
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 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.	**MEDICAL DEVICE**	**MDA**
5.	**Dental Products**			
	i. Fluoride Dental Preparations (e.g., 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**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		d. As a desensitizing agent for the treatment of hypersensitive teeth, for sealing the dentinal tubules for cavity preparations or on sensitive root surfaces or to line cavity preparations under amalgam restorations.	**MEDICAL DEVICE**	**MDA**
	ii. <u>Root Canal Filling Incorporating Antibiotic</u>	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. <u>Oral Wound Dressing, Non – Animal/ Microbial Derived</u> (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. <u>Peritoneal Dialysis Dialysate</u>	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 (e.g., dialysate bag, drainage bag, transfer tubing, linking	**NPRA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
			connector, disc, injection port, overpouch etc.), it will be classified as **Drug-device combination product and shall be regulated as DRUG (refer to No.9. <u>Drug - Delivery Products Regulated as Drug Products</u>)**	
	ii. <u>Haemofiltration Solution</u>	It is used for the exchange of solutes with blood through a system of extracorporeal filters.	**DRUG**	**NPRA**
	iii. <u>Haemodialysis Dialysate</u>	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. <u>Haemodiafiltration Solution</u>	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 DIVISION
7.	**Drug-Eluting Beads** (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, e.g., 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 and shall be regulated as DRUG**	**MDA/NPRA**
8.	**Drug-Eluting Stents (DES)**	For use in angioplasty or coronary stenting procedures.	**Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**
9.	**Drug - Delivery Products Regulated as Drug Products** (e.g., insulin prefilled pen/ syringes, asthma inhalers, intrauterine with hormone action, CAPD products with CAPD system (e.g., 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 DIVISION
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. <u>Eye/Ocular Lubricants, Including Artificial Tears</u>	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. <u>Aqueous/Vitreous Humour Replacement Medium</u>	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**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
	iii. **Cold Sensation Eye Pillow**	To reduce fatigue from work stress or lack of sleep.	**MEDICAL DEVICE**	**MDA**
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 and shall be 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 a Device-Drug combination product and shall be 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**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		b. Disrupting the water balance mechanism of the lice by dissolving and emulsifying off their protective cuticular lipid layer, alters physical characteristics of the egg so that the nymph develops to maturity but cannot hatch.	**MEDICAL DEVICE**	**MDA**
		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.	**Heat Pad/ Cooling Pad**	To relief aches and pains.	**MEDICAL DEVICE**	**MDA**
16.	**In Vivo Diagnostic Agents**	a. Topical/intraocular/intravitreal ophthalmic staining agents/ dyes for diagnostic purpose, enhance visualization during ophthalmic procedures and/or contact lens fitting; e.g., fluorescein ophthalmic strips, trypan blue, brilliant blue, methylene blue.	**MEDICAL DEVICE**	**MDA**
		b. For diagnostic purposes other than No.16a, 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	**DRUG**	**NPRA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		- Radiopharmaceuticals for diagnostic use (e.g., 14C- Urea Capsule for H pylori test) - Hapten preparation for the diagnosis of contact allergy		
		c. As Diagnostic Test Kit consist of drug and analyser	**DRUG-DEVICE combination product regulated as DRUG** **NOTE:** The device component will be regulated on a case to case basis.	**NPRA**
		d. As diagnostic analyser only (without drug)	**MEDICAL DEVICE**	**MDA**
17.	**Irrigation Solutions**	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.	**Local Refrigeration Anaesthesia**	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 anaesthesia. Its principal mode of action is not pharmacological, immunological or metabolic.	**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 DIVISION
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 oxide gas)	**DRUG**	**NPRA**
		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>** (e.g., 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</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 DIVISION
23.	**Oral Care Products**			
	Artificial Saliva/ Saliva Substitute/ Replacement	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, 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.	**Other Topical Antiseptics/ Disinfectants**			
	i. Swabs/ Wipes Containing Antiseptics/ Disinfectants/ Antimicrobial Substances (e.g., chlorhexidine, iodine, cetrimide)	For use on human skin and intended to be used for a medical purpose, e.g., pre/ post injection, wound cleaning etc.	**DRUG**	**NPRA**
	ii. Preparations (Including Swabs/ Wipes) Containing Antiseptics/ Disinfectants/ Antimicrobial Substances (e.g., alcohol, chlorhexidine, iodine, cetrimide)	Intended for the disinfection of medical devices.	**MEDICAL DEVICE**	**MDA**
	iii. Alcohol Only Wipes/ Swabs	To be used for a medical purpose to wipe intact skin for needles access	**MEDICAL DEVICE**	**MDA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
25.	**<u>Peeling/ Exfoliator Products</u>** (e.g., 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. <u>Personal Intimate Hygiene</u>	a. For female/ male intimate hygiene **NOTE:** The product should be rinsed off.	**COSMETIC**	**NPRA**
		b. For symptomatic relief of vaginal irritation/ infections by changing the vaginal pH.	**MEDICAL DEVICE** (If it contains a pharmacologically active substance, it may be classified as **DRUG)**	**MDA**
	ii. <u>Vaginal Douche</u>	Vaginal douching is the process of intravaginal cleansing with a liquid solution for: - personal hygiene or aesthetic reasons - preventing or treating/ managing vaginal infections	**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 DIVISION
		- 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 douche is to be used as a cleanser and it should not be used as a contraceptive		
	iii. <u>Hand Sanitizer</u> (e.g., gel, foam, liquid)	For general hand hygiene without therapeutic claims.	**COSMETIC**	**NPRA**
	iv. <u>Personal Intimate Lubricant</u>	To use as a vaginal lubricant during the climaterium (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.	**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 DIVISION
27.	**<u>Skin Barrier Product</u>** (e.g., 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.	**<u>Soft Tissue Filler/ Dermal Filler</u>**	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 pharmacologically active substance, such as local anaesthetic, e.g., lidocaine, it will be classified **as a Device-Drug combination product and shall be regulated as MEDICAL DEVICE)**	**MDA**
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, such as local anaesthetic e.g, lidocaine, it will be classified as a **Device-Drug combination product and shall be regulated as MEDICAL DEVICE)**	**MDA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
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**
31.	**<u>Wart Products</u>** (e.g., pen applicator containing a caustic agent, cyryogenic kit with refrigerant)	a. Containing a caustic agent e.g., trichloroacetic acid (TCA) that destroys warts by chemical coagulation of proteins.	**DRUG** **NOTE:** If a device component is present, it will be regulated on a case to case basis	**NPRA**
		b. Cryotherapy that destroys warts by freezing them using a very cold substance e.g., liquid nitrogen or refrigerant made from dimethyl ether and propane.	**MEDICAL DEVICE**	**MDA**
32.	**<u>Wound Care/ Treatment Products</u>**			
	i. <u>Comprising A Matrix</u> (e.g., dressing, gauze, swabstick, plaster, sponge)	a. To administer a medicinal substance to the wound, e.g. antimicrobial/ antiseptic agent for the purpose of controlling infection.	**DRUG**	**NPRA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		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 e.g., antimicrobial/ antiseptic agent.	**MEDICAL DEVICE**	**MDA**
	ii. <u>Comprising A Matrix, Typically Of Living Cells (Fibroblasts) And/ Or Structural Proteins</u>	To facilitate the infiltration of native skin elements (e.g., fibroblasts, leukocytes, blood vessels) for skin regeneration.	**MEDICAL DEVICE**	**MDA**
	iii. <u>Topical Preparation For Application To A Skin Wound</u> (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. <u>Deep Cavity Wounds Dressing For Application To A Surgical Wound</u>	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. <u>Silver-Containing Topical Preparations For Application To A Skin Wound</u> (e.g., silver nitrate/ silver sulfadiazine/ colloidal silver gel, cream)	a. To administer/ apply an antiseptic/ antimicrobial to wounds for the purpose of treating infection	**DRUG**	**NPRA**

NO.	PRODUCT	INTENDED PURPOSE/ INDICATION AND MODE OF ACTION (MOA)	CATEGORY	CUSTODIAN DIVISION
		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 ancillary medicinal substance	**MEDICAL DEVICE**	**MDA**
	vi. <u>Intravascular Catheter Securement Device Containing Antimicrobial/ Antiseptic Agent</u> (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**

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