SUMMARY OF MEDICAL DEVICE-DRUG-COSMETIC INTERFACE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO.	PRODUCT	INTENDED PURPOSE OR INDICATION	CATEGORY
1	**Eye Lubricant**	A sterile substance used to provide supplemental lubrication/hydration to the natural eye to treat dry, tired, and/or strained eyes resulting from dry eye syndrome, ageing/hormone changes (menopause), or environmental factors (e.g., pollution and air conditioning).	**MEDICAL DEVICE**
2	**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 pharmacologically active substance, it will be classified as **DRUG**)
3	**Medical gases**	To be used in anaesthesia and inhalation therapy, including their primary containers.	**DRUG**
4	**Medical gases**	For **in-vivo** diagnostic purposes including lung function tests.	**DRUG**
5	***In vivo* diagnostic agents**	For diagnostic purposes, carrier solutions to stabilize micro bubbles for ultrasound imaging.	**DRUG**
6	**Hyaluranon based products** used as; ***i- Synthetic-fluid tissue reconstructive material***	To correct cutaneous deformities of the skin (e.g., wrinkles, folds, scars), particularly in cases of ageing or degenerative lesions, or 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.	**MEDICAL DEVICE**
	ii- Synovial joint replacement fluid (Joint lubricant)	To help cushion the joint, especially in cases of endogenous synovial fluid reduced viscosity from degenerative disease.	**MEDICAL DEVICE**
	iii- 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**
7	**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**
8	**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**

SUMMARY OF MEDICAL DEVICE-DRUG-COSMETIC INTERFACE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO.	PRODUCT	INTENDED PURPOSE OR INDICATION	CATEGORY
9	**Fluoride dental preparations** ***i- Oral care product.***	To maintain oral hygiene.	**COSMETIC** (If concentration of fluoride is less than or equal to 1500ppm)
		To maintain oral hygiene and prevent oral diseases.	**DRUG** (If concentration of fluoride is more than 1500ppm)
	ii- Fluoride dental preparations with a typical device mode of action.	To provide filling to the cavity and provide layer for diseases prevention.	**MEDICAL DEVICE**
10	**Wound treatment product** ***i- comprising a matrix***	To administer medicinal product.	**DRUG**
	ii- comprising a matrix	To provide protective layer/barrier to prevent microbial penetration and create healing environment.	**MEDICAL DEVICE**
	iii- providing 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**
	iv- topical application to a skin wound (e.g., abrasion, laceration, cut, ulcer)	To facilitate local haemostasis primarily through haemoglobin binding. 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**
	v- topical application to a skin wound	To provide and maintain a moist internal environment for wounds to assist the healing process.	**MEDICAL DEVICE**
11	**Medicated health patch**	To relieve fatigue, body aches, joint pains; or	**DRUG**
		To regulate hormone imbalance	

SUMMARY OF MEDICAL DEVICE-DRUG-COSMETIC INTERFACE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO.	PRODUCT	INTENDED PURPOSE OR INDICATION	CATEGORY
12	**Personal Intimate Hygiene Product (Rinse off)**	For the female intimate hygiene.	**COSMETIC**
13	**Personal Intimate Lubricant**	To be used as vaginal lubricants 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**
		To be used for symptomatic relief of vaginal irritation by lowering the pH value.	**DRUG**
14	**Root canal filling incorporating antibiotic**	To seal the canal and disinfecting 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.	Drug-device combination product regulated as **MEDICAL DEVICE**
15	**Synthetic-fluid tissue reconstructive material** (Soft tissue filler incorporating local anaesthetic)	It is used for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) and local anaesthetic is an ancillary medicinal substance to provide patients with a more comfortable injection experience during procedure.	Drug-device combination product regulated as **MEDICAL DEVICE**
16	**General Purpose Surgical Drape** 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 the product/device does not contain Iodine or if concentration of iodine is less than 2%) **DRUG** (If the product/device contains Iodine ≥ 2%)
17	**Wart Cryogenic Kit** A refrigerant made from dimethyl ether and propane.	To freeze superficial skin lesions (e.g., warts) for their destruction and removal.	**MEDICAL DEVICE**

SUMMARY OF MEDICAL DEVICE-DRUG-COSMETIC INTERFACE (MDDCI) PRODUCT CLASSIFICATION DECISION

NO.	PRODUCT	INTENDED PURPOSE OR INDICATION	CATEGORY
18	**Pressure-ulcer Topical Dressing** A solution or emulsion designed to be applied to dermal pressure sores.	To prevent and treat pressure/decubitus ulcers and lower extremity ulcers. It is intended primarily to create a barrier between the skin lesion(s) and the external environment to promote protection and healing.	**MEDICAL DEVICE**
19	**Hand Sanitizer**	For general hand hygiene	**COSMETIC**

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 CONTROL BUREAU, Ministry of Health Malaysia.**
- **Drug-Device Combination Product** will be regulated according to the classification that has been made and by the relevant agencies.

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