General information for the Amendment of Annex I to Article 3 and Article 8 of “The Regulations for Governing the Management of Medical Device”

Regarding to the wide range of scientific fields involved in medical equipment and variety of device types, items and components involved with rapid technological innovation, this notice is amending the contents of annex I to article 3 of “The Regulations for Governing the Management of Medical Device.” In order to clarify the classification description, intended use situations and to harmonize with international regulatory trends to in line with the current situation, the regulation is to be amended. Considering a transition period is necessary for manufactures to comply with the new requirements, the contents of article 8 of the regulation is amended accordingly.

Amendment of article 8 of “The Regulations for Governing the Management of Medical Device”

Amended Article	Current Article	Description
Article 8 The regulations shall be implemented on the date of announcement, except the manufacturing of Optical Impression Systems for CAD/CAM (Classification Number: F.3661) under the amendment of Article 3 Item 2 Annex 1 on January 7th, 2014, shall comply with this regulation from July 1st, 2014. The manufacturing of Quality Control Material (assayed and unassayed) (Classification Number: A.1660), Ear, Nose, and Throat Drug Administration Device (Classification Number: G.5220), and Corrective Spectacle Lens (Classification Number: M.5844) under the amendment of Article 3 Item 2 Annex 1 on June 3rd, 2015, shall comply with this regulation from September 1st, 2016.	Article 8 The regulations shall be implemented on the date of announcement, except the manufacturing of Optical Impression Systems for CAD/CAM (Classification Number: F.3661) under the amendment of Article 3 Item 2 Annex 1 on January 7th, 2014, shall comply with this regulation from July 1st, 2014. The manufacturing of Quality Control Material (assayed and unassayed) (Classification Number: A.1660), Ear, Nose, and Throat Drug Administration Device (Classification Number: G.5220), and Corrective Spectacle Lens (Classification Number: M.5844) under the amendment of Article 3 Item 2 Annex 1 on June 3rd, 2015, shall comply with this regulation from September 1st, 2016.	Regarding to the implementation date of Rapid Screening System for Influenza Virus Antigen (Classification Number: C.3328), Surgical Gloves (Classification Number: I.4460), Patient Examination Gloves (Classification Number: J. 6250)" and Mechanical Wheelchair (Classification Number: O. 3850) under the amendment of Article 3 Item 2 Annex 1 on January 1st, 2019, the amendments should be implanted one year after the official announcement. Therefore the manufacturers can have sufficient time to comply with the regulations.

The manufacturing of Rapid Screening System for Influenza Virus Antigen (Classification Number: C.3328), Surgical Gloves (Classification Number: I.4460), Patient Examination Gloves (Classification Number: J. 6250)" and Mechanical Wheelchair (Classification Number: O. 3850) under the amendment of Article 3 Item 2 Annex 1 on July 29, 2019, shall comply with this regulation from July 29, 2020.		

Amendment of Annex 1 to Article 3 of "The Regulations for Governing the Management of Medical Device"

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
C.3328	Influenza virus antigen detection test system	2	An influenza virus antigen detection test system is a device for qualitative (rapid screening) detection of influenza virus infection directly from clinical specimens of patients with respiratory symptoms and signs. The test aids in the diagnosis of influenza infection and provides epidemiological information on influenza. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of these devices. Because influenza is highly contagious and may lead to an acute respiratory tract infection causing severe illness and even death, the accuracy of these devices has serious public health implications.					1. New classification. 2. Reference to US FDA 2017 new regulation number (866.3328).

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
C.3330	Influenza virus serological reagents	1	Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.This classification does not include devices for qualitative (rapid screening) detection of influenza virus infection directly from clinical specimens of patients with respiratory symptoms and signs.	C.3330	Influenza virus serological reagents.	1	Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.	1. Modification of the classification name and description. 2. Reference to CDC “influenza virus” mandarin (Chinese) terminology. Amendment the description to distinguish with the classification Influenza virus antigen detection test system (C.3328).
D.5905	Noncontinuous ventilator (IPPB) and accessories	2	A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) and accessories are the device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. This device is intended to use with accessories such as masks of noncontinuous ventilator.	D.5905	Noncontinuous ventilator (IPPB)	2	A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is the device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.	1. Modification of the classification name and description. 2. This amendment includes accessories such as masks of discontinuous breathing apparatus (ventilators) in this classification. In order to avoid confusion between this classification Nonrebreathing mask (D. 5570) and Oxygen

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
								mask (D.5580), the classification name and identification are revised accordingly.
G.5220	Ear, nose, and throat drug administration device and contained substance	1,2	(a)Description. An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.(b)Classification: Class 1: The device does not contain substance (liquid or other substance),If the device contains flushing solution or other substance (solution, solute, powder and etc.) for its intended purpose, and the solution or substance used in combination with the device is not regulated as a medicinal substance.	G.5220	Ear, nose, and throat drug administration device.	1,2	(a)Description. An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the power blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.(b) Classification: (1) Class 1: The device does not contain liquid. (2) Class 2: The device contains flushing liquid which is not regulated as a medicinal substance.	1. Modification of the classification name and description. 2. Modification of the classification description to include other substance containing in the device. Correction of the typo (power to powder).

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
H.5320	Nonimplanted electrical continence device.	2	A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This classification excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (L.5940).	H.5320	Nonimplanted electrical continence device.	2	A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This classification excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (L.5940).	1. Modification of the classification description. 2. The original identification describes only battery-powered nonimplanted electrical continence devices. This amended description extended to include AC-powered nonimplanted electrical continence devices.
I.4460	Surgeon's glove.	1,2	A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded. A surgeon's glove containing biodegradable powders which complies with U.S.P. (for example corn powders) is class 2 device.Non-clinical performance data of the barrier property (water	I.4460	Surgeon's glove.	1,2	A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.A surgeon's glove containing biodegradable powders which complies with U.S.P. (for example corn powders) is class 2 device.	1. Modification of the classification description. 2. In order to improve product safety, effectiveness and quality, glove products should comply with standards. Regarding to the international trend of banning powdered gloves, this classification provides

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
			leak) and tensile strength should comply with ISO 10282, ASTM D 3577, EN 455 or equivalent standards.A non-powdered (powder free) surgeon's glove should comply with EN ISO 21171, ASTM D 6124 or equivalent standards. The amount of residual powders on a glove should not exceed 2.0 mg.					guidance on examining non-powdered (powder free) gloves.
J.6250	Patient examination glove.	1	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.Materials of patient examination gloves should comply with the barrier property (water leak) and tensile strength requirements of ISO 11193-1, ASTM D 3578, ASTM D 5250, ASTM D 6319, EN 455 or equivalent standards.A non-powdered (powder free) patient examination glove should comply with residual powders requirements of EN ISO 21171, ASTM D 6124 or equivalent standards. The amount	J.6250	Patient examination glove.	1	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	1. Modification of the classification description. 2. In order to improve product safety, effectiveness and quality, glove products should comply with standards. Regarding to the international trend of banning powdered gloves, this classification provides guidance on examining non-powdered (powder free) gloves.

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
			of residual powders on a glove should not exceed 2.0 mg.					
O.3800	Motorized vehicle for medical purposes	2	A motorized vehicle for medical purposes is a gasoline-fueled or battery-powered device intended for medical purposes that is used for transportation by mobility disabled persons. The maximum speed limit of motorized vehicles for medical purposes is 10 km/h.	O.3800	Motorized vehicle for medical purposes	2	A motorized vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons. The maximum speed limit of motorized vehicles for medical purposes is 10 km/h.	1. Modification of the classification description. 2. The classification description is amended to clarify that a motorized vehicle for medical purposes is used for transportation by mobility disabled persons.
O.3850	Mechanical wheelchair.	1	A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.Mechanical wheelchairs shall comply with the performance requirements of national standard CNS 14964-8, ISO 7176-8 or equivalent international standards.	O.3850	Mechanical wheelchair.	1	A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.	1. Modification of the classification description. 2. In order to improve the product quality, mechanical wheelchairs shall comply with product standards similar to requirements of other

Amended regulation				Current regulation				Description
Classification number	Classification name	Class	Description	Classification number	Classification name	Class	Description	
								countries.
O.3860	Powered wheelchair.	2	A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.The maximum speed limit of powered wheelchairs is 10 km/h. This classification contains external power components for use in mechanical wheelchairs	O.3860	Powered wheelchair.	2	A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.	1. Modification of the classification description. 2. Regarding to the product safety, this classification defines maximum speed limit of powered wheelchairs. Since the risk of external power components for use in mechanical wheelchairs is similar to similar motorized vehicles for medical purposes (O.3800), this classification includes external power components for use in mechanical wheelchairs.