
First published in the *Government Gazette*, Electronic Edition, on 4th April 2012 at 5.00 pm.

No. S 140

**HEALTH PRODUCTS ACT
(CHAPTER 122D)**

**HEALTH PRODUCTS
(MEDICAL DEVICES) (AMENDMENT)
REGULATIONS 2012**

In exercise of the powers conferred by section 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) (Amendment) Regulations 2012 and shall come into operation on 5th April 2012.

New regulation 10A

2. The Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (referred to in these Regulations as the principal Regulations) are amended by inserting, immediately after regulation 10, the following regulation:

“Exception for certain Class A medical devices

10A. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a Class A medical device —

- (a) which is listed in the first column of the Sixth Schedule;
- (b) which is not of or does not bear a description or an intended purpose which is substantially different from the description or intended purpose described in the second column of that Schedule; and
- (c) which is not intended to be supplied in a sterile state.”.

Amendment of regulation 11

3. Regulation 11(1) of the principal Regulations is amended —
- (a) by deleting the words “1st September 2011” in sub-paragraph (b)(vi) and substituting the words “1st December 2011”;
 - (b) by deleting the word “and” at the end of sub-paragraph (d); and
 - (c) by deleting the full-stop at the end of sub-paragraph (e) and substituting the word “; and”, and by inserting immediately thereafter the following sub-paragraph:

“(f) the retail supply, at any time, by a retail supplier of an unregistered Class A or B medical device that the retail supplier has taken possession of on or after 10th August 2010 but before 5th April 2012.”.

New Sixth Schedule

4. The principal Regulations are amended by inserting, immediately after the Fifth Schedule, the following Schedule:

“SIXTH SCHEDULE

Regulation 10A

	<i>First column</i>	<i>Second column</i>
	Device identifier	Description or intended purpose
1.	Adhesive bandage	A piece of fabric or plastic material (not a strip) that is applied to a part of the body with a pressure-sensitive adhesive. It may or may not include an absorbent pad. It is used to cover and protect intact skin or wounds, to approximate the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin. This is a single-use device.
2.	Adhesive strip	A small, narrow flexible band (of fabric, plastic, paper or other material) coated on one side with a pressure-sensitive adhesive, used to cover and protect intact skin or wounds or approximate the edges of superficial wounds or fix dressings to skin. The device may include an adhesive pad and have qualities such as hypoallergenic or waterproof. The device is usually supplied in pre-cut sizes or shapes. This is a single-use device.

SIXTH SCHEDULE — *continued*

	<i>First column</i>	<i>Second column</i>
	Device identifier	Description or intended purpose
3.	Adhesive tape	A very long and narrow flexible band (of fabric, plastic, paper or other material) coated on one side with a typically pressure-sensitive adhesive, used to cover a surface (e.g. small wound), fix a dressing, or bind/attach objects (e.g. a venflon to a patient's body part, an orthopaedic cast). The device may also be applied in several layers, one overlapping the other, to cover and exert pressure on a body part (e.g. a limb). The device may have additional properties (e.g. waterproof, hypoallergenic) and is typically supplied in rolls. This is a single-use device.
4.	Adhesive tape remover	A solvent material designed to remove adhesive tape and its residue from the skin or other surfaces. This is a single-use device.
5.	Applicator, absorbent tipped	A device used for making local applications to any accessible body surface. It is typically designed as a slender rod of wood, flexible metal or a synthetic material, to which is attached a non-sterile absorbent tip at one end. This is a single-use device.
6.	Nasal aspirator, manual	A portable, hand-held, manual suction device designed to enable gentle suction and clearing of excessive mucus from the nasal passages to facilitate easier breathing. It is available in a variety of forms including a compressible bulb with a tube that is inserted into the nares, or a syringe with a small bulb at its distal end that is applied to the nasal opening.

SIXTH SCHEDULE — *continued*

	<i>First column</i>	<i>Second column</i>
	Device identifier	Description or intended purpose
7.	Ice bag	A flexible container (a bag) designed to be filled with ice to provide dry cold therapy to a limited external surface area of the body. It is typically made of plastic or rubber materials with a detachable cap that can be threaded or fixed to the bag once it is filled with ice. It may include a holder or attachments to facilitate fixing or holding the device in place against the body surface of the patient. It can be used to alleviate pain and/or promote healing in minor injuries of the body, or for application around the neck or limbs.
8.	Bandage, self-adherent	A flexible piece, strip, or roll of fabric or plastic material that is applied to (typically wrapped around) a part of the body to secure a dressing, maintain pressure over a compress, or immobilise a limb or other body part. This is a single-use device.
9.	Bandage, clavicle	A strip or roll of fabric or webbed material that is wrapped around the shoulder girdle to maintain fixation and longitudinal extension of the clavicle during a period of treatment. This is a single-use device.
10.	Bandage, elastic	An elasticised fabric (e.g. polyamide, lycra) used to provide support or local pressure to a part of the body, especially a joint, while allowing movement. It may have various configurations (e.g. long flat strip, tubular) to accommodate various body parts (e.g. ankles, knees, wrists, neck). This is a single-use device.
11.	Bandage, gauze	A piece or strip of fabric made of open weave cotton or rayon fibres and of differing degrees of fineness used to cover and protect wounds. This is a single-use device.
12.	Bandage, gauze, roller	A long, layered gauze supplied in rolls that is used to bandage heads, limbs and wounds that are difficult to dress (e.g. burns, plastic surgery or orthopaedic wounds). This is a single-use device.

SIXTH SCHEDULE — *continued*

	<i>First column</i>	<i>Second column</i>
	Device identifier	Description or intended purpose
13.	Bandage, traction	A large strip of fabric or plastic material used to assist in exerting desirable tensile (pulling) forces on the body. This is a single-use device.
14.	Sitz bath	A tub that is filled with heated water and intended for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatised tissues of the perianal and perineal areas. The patient immerses only the hips and buttocks, keeping the legs outside of the tub. It is typically used to maintain patient hygiene and to alleviate pain and discomfort caused by haemorrhoids, uterine cramps, labour and/or other diseases of the pelvic, abdominal and perineal area (e.g. prostate, bladder, bowel, vaginal disorders). This is a non-active medical device.
15.	Bed, hospital	A device upon which a patient rests or sleeps, or upon which a patient may be treated. It is used in hospitals, institutions and home care and is used in conjunction with a patient's admission and treatment, or for the disabled or infirm.
16.	Bed, general-purpose, manually-operated	A mechanically-designed bed to be used as a general-purpose patient bed in hospital wards with manual mechanisms to adjust the height and surface contour of the bed. This device may include movable and latchable side rails.
17.	Bed, general-purpose, hydraulically-powered	A bed designed to be used as a general-purpose patient bed in hospital wards with a hydraulic mechanism to adjust the height and surface contour of the bed. This device may include movable and latchable side rails.
18.	Bed, general-purpose, electrically-powered	A bed designed to be used as a general-purpose patient bed in hospital wards and which is electrically powered (motorised), providing the patient/nursing staff with touch button adjustment possibilities.