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

	First column	*Second column*
	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*

	First column	*Second column*
	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*

	First column	*Second column*
	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*

	First column	*Second column*
	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.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
19.	**Bedpan, fracture**	A device used by a bedridden patient as receptacle for urine and faeces and which is designed to be used by a patient whose hips have been plastered. This device is reusable after the appropriate cleaning procedure has been done.
20.	**Bedpan, general-purpose**	A device used by a bedridden patient as receptacle for urine and faeces. This device is reusable after the appropriate cleaning procedure has been done.
21.	**Abdominal binder**	A strip or roll of fabric or plastic material applied to the abdomen to support relaxed abdominal walls.
22.	**Ankle binder**	A strip or roll of fabric or plastic material designed to support the ankle joint.
23.	**Breast binder**	A strip or roll of fabric or plastic material designed to support the breasts.
24.	**Chest binder**	A strip or roll of fabric or plastic material designed to support the ribs and chest.
25.	**Binder, sternum**	A strip or roll of fabric or plastic material designed to support the sternum.
26.	**Wrist binder**	A strip or roll of fabric or plastic material designed to support the wrist joint.
27.	**Blanket, rescue**	A large piece of fabric-material blanket specially designed to keep a patient warm and/or to prevent the further loss of body heat in an emergency situation.
28.	**Bite block**	A device inserted into a patient's mouth to maintain oral patency during an endoscopic procedure primarily to protect the endoscope, introduced via the mouth, from the patient's natural tendency to bite down on the instrument. The device will also protect the tongue and teeth of the patient during endoscopy. This is a single-use device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
29.	**Adaptor, blood collecting tube, reusable**	A non-sterile reusable device used to attach and hold a venous access device (i.e. needle, blood collection set) during venipuncture and to connect these devices to the blood collection tube.
30.	**Blood collection tray**	A device intended to hold syringes and other apparatus needed for blood collection.
31.	**Stripper, blood tubing**	A device specifically designed to strip, crimp and cut tubing in the preparation of blood segments from the blood collection and processing procedures.
32.	**Tube, blood collecting, open**	A non-sterile device designed as a tube which is used during the collection of blood. It is open-ended, allowing blood to fill the tube from, for example, a tubing that has been inserted. The tube may or may not be sealed using a cap or plug. This is a single-use device.
33.	**Tube, blood collecting, sealed, evacuated**	A non-sterile device designed as a tube which is used with a blood collection tube adaptor and a blood collection needle to draw blood. This device is a presealed tube which has been partially evacuated. The vacuum will make the tube fill with blood. This is a single-use device.
34.	**Board, arm**	A firm device in which a patient's arm is placed for stabilisation to maintain the patency of an intravascular catheter (e.g. those connected to an intravenous or intra-arterial line). It is typically constructed of expanded polystyrene with a plastic coating and can be straight or curved to accommodate the patient's arm/wrist.
35.	**Board, cardiac compression**	A flat, rigid device that is placed under a patient to instantly give the necessary support required for the application of cardiopulmonary resuscitation. This device is typically suitable for use when an acute situation has arisen and the patient is lying in his bed.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
36.	**Board, spinal**	A flat, stiff device placed on a stretcher to ensure spinal immobilisation when a spinal injury is suspected.
37.	**Bottle, heating/cooling**	A flexible container, typically with a relatively narrow neck, that is usually filled with either hot or cold water or ice for the purpose of applying heat or cold therapy to an area of the body.
38.	**Contact lens case**	A container designed for the storage of contact lenses when the lenses are not being used. The container is composed of chemically inert material(s).
39.	**Chair, bath/shower**	A device designed to be sat upon by a person who is either bathing, showering, or using some washing facility where there is a need to sit, such as because the person is disabled or infirm, or because it is part of medical treatment.
40.	**Chair, blood donor**	A device used to position the patient in such a manner that a technician/nurse has easy access to the patient's arm for drawing blood. The arm board, that is attached to the chair, has lateral and height adjustments so that the patient's arm can be positioned in a location that is easily accessible to whoever is drawing the blood sample. This chair can typically be tilted/moved so that the patient lies in a reclining position.
41.	**Chair, examination/ treatment**	A device used to position the patient in a sitting, semi-sitting or reclined posture for easy access and patient comfort during an examination, treatment, or surgical intervention.
42.	**Chair, toilet**	A chair designed with a toilet-like seat that allows an immobilised person/patient to utilise a standard stationary toilet without leaving the chair.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
43.	**Chair, MRI system**	A chair or stool specifically designed to support and position a patient during an examination involving the use of a diagnostic magnetic resonance imaging (MRI) system. For MRI system compatibility, these chairs/stools are made of ferromagnetically inactive materials.
44.	**Charger, battery**	A mains electricity (AC-powered) device designed to supply an electrical charge to the rechargeable batteries or battery pack of a medical device, restoring the batteries or battery pack to an appropriate working condition. This device is typically connected to the building's mains electricity power supply and can be used to charge the batteries either by themselves (removed from their parent device) or whilst they are still inside the parent device (in situ), e.g. a defibrillator, an ophthalmoscope, an otoscope. This device usually has current and voltage controls to meet the charge needs of different types of batteries.
45.	**Chart, eye, Amsler grid**	An ophthalmic device that consists of a series of charts with grids of different sizes that are held at a distance of 30 cm from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.
46.	**Chart, eye, colour discrimination**	An ophthalmic chart with coloured figures printed on coloured backgrounds, used in testing colour vision.
47.	**Chart, visual acuity**	An ophthalmic chart imprinted with block letters or other symbols in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; used in testing visual acuity. Such charts are often combined in a box where the individual letters or symbols are selected and highlighted by the optician/doctor with background electrical lighting.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
48.	**Syringe, high performance/calibration, liquid/gas chromatography**	A dedicated syringe used for injecting small volumes of accurately measured amounts of liquid or gas into a chromatograph system, such as for calibration or reference. This device is typically made of a glass cylinder with a steel plunger and made to high tolerances of accuracy. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
49.	**Indicator, cellulose fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
50.	**UV light, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
51.	**Indicator, alumina fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
52.	**Indicator, silica gel fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
53.	**Plate, alumina, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
54.	**Papers, ion exchange**	For use in ion exchange chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
55.	**Resins, ion exchange, liquid chromatography**	For use in ion exchange chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
56.	**Centrifuge, laboratory**	A device that is a laboratory centrifuge used to separate the components of suspensions by the application of centrifugal force. It typically consists of an electrically-powered drive unit with a vertical shaft and horizontal rotor attached to the upper end. This device is intended to centrifuge patient samples (e.g. body fluids) either alone or after the addition of reagents or other additives before measuring analytes. It is typically a low-speed (up to 6,000 rpm) or medium-speed (up to 12,000 rpm) machine. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
57.	**Centrifuge, ultra**	A device that is a laboratory centrifuge used to separate the components of suspensions by the application of centrifugal force. It typically consists of an electrically-powered drive unit with a vertical shaft and horizontal rotor attached to the upper end. This device is a specialised centrifuge that processes relatively small volumes of sample at very high speeds, typically up to 100,000 rpm and RCF 800,000 xg. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
58.	**Cover, microscope slide**	A device or material used as a physical barrier to protect the surface of a microscope slide upon which a sample has been placed from the effects of mechanical and/or environmental exposure. This is a single-use device. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
59.	**Slide, microscope**	A device, typically a thin flat piece of glass of given dimensions, whereupon samples (e.g. blood, tissue) can be placed for analysis, usually under a microscope. This is a single-use device. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
60.	**Petri dish processor**	A laboratory instrument that automatically processes petri dishes, feeding them from a magazine and filling them with a given quantity of substance, e.g. agar (a gelatine-like substance derived from seaweed used as a stabiliser and for nutrition) prior to the production of micro-organism cultures, for diagnostic purposes. This can be used together with an agar steriliser. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
61.	**Pipette, electronic/ manually-operated**	A device typically used in the laboratory to transfer discrete and consistent volumes of liquid substances, e.g. into a test tube or the wells of a microtitre plate. This device can operate mechanically, electronically, or through manual induction. The device may be factory pre-set to deliver a given volume, or may have user-selectable volumes within a useful volume range. It includes the pipette tips, safety mouthpiece and shield. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
62.	**Incubator, laboratory**	A device designed for use in a laboratory setting to provide controlled conditions for the incubation of biological and chemical materials. It will typically maintain a desired environment of, for example, temperature, gas concentrations or humidity. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
63.	**Inoculating loop**	A device consisting of a slender handle and an attached wire loop used to gather and hold specimen material (e.g. bacterial growth colonies) for the purpose of inoculating a culture medium (e.g. agar or broth). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
64.	**Mixer, laboratory**	A device, typically used in the laboratory, for the mixing of 2 or more components by using a slow stirring/blending movement. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
65.	**Sample processing system**	An automated group of devices without analysers (e.g. robotic conveyors, handlers) controlled by a computer system used to alternate and treat clinical samples in preparation for analysis. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
66.	**Sample alternating system**	An automated group of devices without analysers composed of robots/conveyors and a computer control system used to rotate clinical samples for processing and analysis. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
67.	**Sample processor**	An instrument without analysers used to automatically prepare a clinical sample for analysis. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
68.	**Sample processor, immunoassay**	An instrument or apparatus intended to homogenise a sample taken from human tissue and to prepare a portion of the sample for analysis by immunoassay analysers. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
69.	**Sample tube vacutip inserting device**	A laboratory instrument that introduces small tube-like tips (vacutips) into the rubber corks/ plugs of sample tubes. This procedure will prevent the evaporation of the sample, and sampling (automatic or manual) can easily be performed through the inserted tip. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
70.	**Shaker, laboratory**	A device, typically used in the laboratory, that shakes or stirs samples/mixtures with a rapid and forceful movement. It is specially used to prevent substances comprising different components from separation or sedimentation because of their different densities. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
71.	**Thermostat, laboratory**	A device used in laboratories to regulate the temperature of various media in association with a parent device (e.g. water in water baths). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
72.	**Washer**	A device used in the clinical laboratory to wash loosely adherent cells or to wash away residuals before diagnostic testing. It may have flexible washing options from simplicity of operation to digitally controlled aspiration and dispensing pumps. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
73.	**Clip, nose**	A device used to help prevent air movement through the nares. The device is typically constructed of plastic with rubber or foam tips and is used during pulmonary function studies to help ensure that airflow is conducted through the mouthpiece for accurate measurements.
74.	**Clip, spectacle, ophthalmic**	A device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or set of spectacles during vision testing.
75.	**Collector, general**	A non-sterile small container for medical treatment purposes or intended for the purpose of short-term storage and/or transportation, to collect fluids, gas or other materials from the human body. This may also be for specimen or sample purposes.
76.	**Collector, sweat**	A non-sterile container used for collecting sweat typically for specimen or sample purposes.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
77.	**Collector, urine**	A non-sterile small container used for collecting urine to obtain a specimen for analysis. This is a single-use device.
78.	**Compression dressing**	An elastic material that is designed to compress a local area (e.g. to stop bleeding, prevent oedema or provide support for varicose veins or ostomy aids).
79.	**Compression garment**	An elastic material that is contoured to fit over and apply pressure to one or more specific body parts (e.g. thighs, hips, buttocks), and is typically used after an invasive procedure (e.g. liposuction). In the case of significant subcutaneous tissue removal (e.g. fat removal after liposuction), the device may aid in the readjustment of overlying skin. This is a reusable device.
80.	**Sterilisation container**	A device used to hold surgical instruments, typically units (e.g. surgical powered drills, saws and their hoses) but also other instruments during sterilisation and for their subsequent storage. The container is permeable in order to allow moisture to escape from within after the sterilisation process is finished, whilst protecting the contents from being contaminated. It may have features such as expiry date, sterile breathing filter or stacking abilities.
81.	**Digital imaging cassette**	A device (e.g. a cassette or barrier envelope) used in medical imaging applications to hold and shield an attached storage phosphor screen from exposure to room light during transport and insertion into a diagnostic imaging X-ray system or a computed radiography scanner, in the process of producing a digital image of a patient radiation pattern.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
82.	**X-ray film cassette, manual**	A device used in medical imaging applications to shield X-ray film from exposure to room light during transport and insertion into a diagnostic imaging system, film formatter or film processor. It is typically designed for use with a particular imaging system or image formatting unit and consists of a plastic or metal housing with removable metal or plastic inserts. Some film cassettes used in X-ray applications can incorporate an X-ray grid into the cassette design.
83.	**Cotton ball**	A spherical mass of cotton or man-made fibres used as a swab to apply medications to or remove liquid from various parts of the body.
84.	**Cotton roll, general-purpose**	A device usually made of medical cotton or sometimes man-made fibres that has a general-purpose use throughout hospitals and other areas of the healthcare sector.
85.	**Cover, thermometer**	A device used as a physical barrier for a thermometer to prevent cross-contamination between patients and/or environmental exposure. This is a single-use device.
86.	**Absorbent point, dental**	A non-medicated absorbent point used in endodontic procedures. This is a single-use device.
87.	**Mixer, dental, amalgam**	A dental amalgamator is a device intended to mix chairside, by shaking, mainly amalgam capsules containing mercury and dental alloy particles immediately before application to the teeth of the patient during dental procedures.
88.	**Articulating paper**	A strip or sheet of suitable material coated with pigment and used for marking areas of contact between opposite teeth, restorations or appliances. This is a single-use device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
89.	**Camera, dental, intra-oral**	A camera specially designed for use during dental surgery to obtain still picture documentation of surgical procedures and to photograph pathologies. This generic device group includes Polaroid, digital and photographic film cameras. This camera is not meant for a diagnostic purpose.
90.	**Chart, dental, colour discrimination**	A device used to determine the correct shade (colour) of filling materials, artificial crowns and teeth for matching to those of the patient.
91.	**Cotton roll, dental**	A device formed as a small, short, cotton roll that is used as a saliva absorber and intended to absorb moisture from the oral cavity during dental procedures. It is usually made of cotton and is disposable.
92.	**Cushion, dental**	A prefabricated or non-custom-made disposable device that is intended for use to improve the fit of a loose or an uncomfortable denture.
93.	**Dental teeth protector**	A curved device designed to fit over the upper and lower sets of teeth to protect them from damage during dental procedures. Such protection can be required when the patient is resisting the dental treatment by clenching his teeth which can be damaged against the metal or plastic materials of the dental instruments being used, and/or if the patient has bad teeth that are susceptible to inadvertent damage.
94.	**Dental ring**	A device used to hold a matrix band and wedge in place around the tooth.
95.	**Dental wedge**	A dental device that is positioned wedge-like at the interdental and cervical area of the teeth during routine intra-oral dental procedures. It is used to slightly separate the teeth during the placement of a filling material, or to stabilise and support other devices (e.g. a matrix band or a rubber dam).

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
96.	**Forceps, dental**	A hand-held dental instrument used in the mouth for different gripping applications. This is a single-use device.
97.	**Light, dental, polymerisation activator**	An electrically-powered lamp used to initiate the polymerisation of dental resin-based materials. The source for the activation should be ultraviolet light. It is used for curing of polymer-based materials in the laboratory.
98.	**Light, dental, intra-oral**	A dedicated light-conducting system with a very small dimension at the light delivery end designed for dental use and to be introduced into the oral cavity. It delivers light using fibre optic cables. The device is typically attached to a dental hand piece and is intended to directly illuminate a patient's oral structures.
99.	**Light, dental, general-purpose**	A dedicated light designed for general-purpose dental use that delivers intense focused lighting to the dental operating, examination or procedure site, which usually is the oral cavity.
100.	**Matrix band/strip, dental**	A matrix band or strip comprising strong material (typically stainless steel or transparent polyester) or a short tube that is used to form a mould around a tooth for the insertion of restorative materials. The device is held snugly around the tooth by a matrix retainer or tensioned around the tooth using a dedicated mechanical tensioning device. The matrix strip, retainer and tensioner may be supplied together or separately.
101.	**Mouth guard, preformed**	A prefabricated device designed to protect the teeth, bones, and tissues of the mouth, from the effects of grinding/clenching of teeth (e.g. bruxism). It is typically made of standard, preformed materials or items for adaptation/ direct insertion in the mouth.
102.	**Mirror, dental, hand-held**	A dental instrument for intra-oral inspection, generally comprising the mirror head and the mirror handle.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
103.	**Placers, dental**	Elastic placers provide an elastic hook on one end and a pusher on the other end to remove dental elastics.
104.	**Retractor, dental**	A dental instrument intended to be used to manually displace soft tissues (e.g. cheeks, lips, tongue) of the oral cavity to improve their visualisation and access, and to afford them protection during oral surgical procedures. This is a single-use device.
105.	**Scaler, dental, manual**	A hand-held dental instrument for removing calculus and other accretions from the surface of teeth during dental cleaning and periodontal therapy. This is a single-use device.
106.	**Aligner tray seater**	A device placed between the upper and lower sets of teeth and bitten down on, or chewed, to seat aligners in the right position.
107.	**Tray, dental**	A device intended to hold solutions, gels and foams for dental treatment.
108.	**Impression tray, dental**	A device intended to hold, support and control the impression material(s) used in making a dental impression (e.g. of a patient's teeth or alveolar process (bony tooth sockets) to produce the structure of a patient's teeth and gums). This device is typically preformed (e.g. horseshoe shaped) and made of metal or plastic materials.
109.	**Depressor, tongue**	An instrument intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
110.	**Surgical drape, general-purpose**	A non-sterile (usually sterilised before use) protective covering made of natural or synthetic materials, or both, designed 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 a catheterisation laboratory). The device may also be used to protect a patient from heat or flame during a surgical procedure.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
111.	**Hammer, percussion**	A metal, usually stainless steel, instrument comprising a handle, shaft and head, used to deliver a force to the body to test reflexes. The handle is designed to fit into the palm of the hand and is usually round, tapering distally into a shaft which terminates at the head. A percussion hammer head comes in various shapes. Some heads are fitted on one or both ends with a material (e.g. rubber or plastic, of various shapes to absorb the shock of the impact). It is also possible for the entire head to be made of rubber or plastic. A percussion hammer is used in neurological examinations.
112.	**Bath, paraffin, laboratory**	A laboratory device used to heat paraffin wax so that it can be used in the fixation of laboratory specimens (e.g. tissue biopsies). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
113.	**Bath, tissue flotation**	A water bath used in conjunction with a microtome during the production of tissue specimens. The tissue specimens float onto the surface of the bath as they are sliced by the operator of the microtome. This device is temperature controlled and is typically used in the laboratory. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
114.	**Cryo spray, histology**	A refrigerant (e.g. dimethyl ether and propane) typically contained in an aerosol dispenser and intended to be used in histology laboratories for freezing tissue specimens in paraffin blocks for sectioning. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
115.	**Microtome blade**	A device that is a flat wedge-shaped blade that has a cutting edge of extreme sharpness and which is mounted into a microtome used to cut micro-slices of tissues that have been fixed, and usually impregnated with paraffin wax. The resulting sections are mounted on glass slides for staining then viewing by microscope. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
116.	**Microtome, rotary, sliding or ultra**	An instrument used for cutting tissue samples into micro-slices in preparation for histological study (microscopic examination). Before cutting, the tissues are fixed (e.g. in paraffin wax, celloidin, plastic), and may be secured to a sample block (a base). For cutting, the sample is held by clamps and the microtome blade/knife is passed over it. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
117.	**Microtome, cryostat**	An instrument that consists of a microtome contained in a temperature controlled cabinet called a cryostat. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
118.	**Stain, microscopy**	An agent used to colour or refract the light of a sample of tissue, cells, blood, or micro-organisms in preparation for light, electron or fluorescence microscopy for diagnostic purposes in clinical laboratories. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
119.	**Tissue processor**	An instrument used in the laboratory for the preparation of tissue specimens prior to examination. It will typically utilise fixation (e.g. encapsulation in a paraffin wax), dehydration, and infiltration techniques to process the tissue samples. This device may be of a manual, semi-automated or fully-automated design. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
120.	**Freezer/dryer, laboratory**	A device typically used in the laboratory for the removal of all moisture (water content) using the process of dry freezing. It is typically constructed as a chamber or receptacle into which the sample or object is placed and the moisture is extracted. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
121.	**Immobiliser, ankle**	A non-rigid device, usually made of a fabric, used to temporarily render the ankle immovable (strait-jacket effect) to support the healing of an injury or a surgical wound.
122.	**Immobiliser, arm**	A non-rigid device, usually made of a fabric, used to temporarily render the arm immovable (strait-jacket effect), typically at the shoulder and elbow, to support healing of an injury or a surgical wound.
123.	**Immobiliser, elbow**	A non-rigid device, usually made of a fabric, used to temporarily render the elbow immovable (strait-jacket effect) to support healing of an injury or a surgical wound.
124.	**Immobiliser, infant**	A device, usually made of fabric and/or plastic materials, used to temporarily render parts of an infant's body (e.g. the arms and/or feet) immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
125.	**Immobiliser, knee**	A rigid support used to temporarily render the knee immovable (strait-jacket effect), either pre-operatively or following injury or arthroscopy.
126.	**Immobiliser, shoulder**	A non-rigid device used to temporarily immobilise or limit abduction of the shoulder joint (strait-jacket effect) to support healing of an injury or a surgical wound. It is typically used post-operatively and for post-traumatic treatment of injuries in the shoulder and upper arm areas (e.g. distortion/contusion, dislocation/luxation, post-operative support). It will typically consist of layered fabric, straps, buckles, fasteners and will eliminate most of the work involved with bandaging.
127.	**Immobiliser, whole body**	A device, usually made of fabric and/or plastic materials, used to temporarily render the patient's whole body immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions.
128.	**Immobiliser, wrist**	A rigid support designed to temporarily render the wrist immovable (strait-jacket effect) as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist. It comes in a variety of sizes.
129.	**Irrigator, nasal**	A device designed to dispense a solution intended to penetrate, clear, and clean the nasal passages and sinus cavity. It typically includes an irrigation bottle/canister, and sometimes actuator tips and adaptors for various solution-delivery applications. The solution may be self-administered for post-operative, preventative or symptomatic nasal care. The device does not include, or is not supplied together with, irrigation solution or medication.
130.	**Irrigation kit, eye**	A device that typically includes an application bottle, syringe or cup, used to flush the eye of irritating particulates/chemicals, or to help stimulate tired eyes. The device does not include, or is not supplied together with, irrigation solution or medication.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
131.	**Knife, paraffin**	A dedicated knife designed to cut paraffin blocks. It will typically consist of a sturdy blade made of hard metal (e.g. beryllium copper) that retains the heat well and a shank that is permanently attached to a hand-held heat source. The heat, which may be regulated, penetrates into the blade from the heat source (e.g. electrical) through the shank. This device is used to cut/handle paraffin in clinical laboratories (histology and pathology embedding). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
132.	**Lens set, trial**	A set of ophthalmic lenses of various dioptric powers intended to be handled or inserted in a trial frame for vision testing to determine the required refraction.
133.	**Light, head-worn**	A device (a lamp) designed to be worn on an operator's head. It is mounted on a band or helmet frame and situated on the user's forehead providing a light directly into the field of vision during surgical, diagnostic or therapeutic procedures. The light typically consists of a magnifying lens, a reflector and a connection for the fibreoptic cable to transfer cold-light or power supply from a battery pack.
134.	**Light, surgical**	A device that provides a specialised light to illuminate a surgical site over a prolonged period of time providing the surgeon(s) with optimal visualisation of small, low-contrast objects at varying depths or through small incisions. In addition to providing enough illumination and minimising the emission of heat to the site, the light will reduce shadows and produce minimal colour distortion, which helps the surgeon evaluate tissues and structures. It typically consists of one or more light bulbs, which reflect the light via reflectors or mirrors depending upon the construction. This device will typically be part of a light system comprising more than one light head.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
135.	**Light, examination, hand-held, battery-powered**	A small hand-held battery-powered light used as a personal light source to provide light for local examination, inspection and treatment of the patient. It may be torch-like in design and can have a magnifying lens to augment the lighting effect. It will typically be found in an examination room, doctor's surgery or office, on a medical trolley or as part of an emergency kit.
136.	**Light, examination**	A device that provides light to illuminate the site of examination or treatment of the patient. It typically consists of one or more light bulbs which reflect the light via reflectors or mirrors depending upon the construction. This device has a variety of uses and can be fixed (e.g. to a ceiling or wall, or supported on a mount). It can also be part of a light system comprising more than one light head.
137.	**Light, ear**	A dedicated device designed to illuminate the ear canal.
138.	**Loupe, binocular**	A system of lenses mounted onto a pair of spectacles worn by the surgeon during surgical intervention. These function as small telescopes and provide a magnified image of the working field. They can also be connected to an external light source supplying light directly through the field of vision.
139.	**Marker, skin**	A device used to make marks on the skin that allow measurement or identification.
140.	**Mask, resuscitation**	A malleable cone placed over the nose and mouth to administer air to a patient during cardiopulmonary resuscitation (CPR). The device is designed to replace mouth-to-mouth resuscitation, therefore avoiding cross-contamination. The device may include an airway, one-way valve or other component.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
141.	**Face barrier, resuscitation shield**	A clear plastic sheet with a filter for mouth-to-mouth resuscitation. It does not provide absolute protection but reduces the risk of cross-contamination. The device does not include an airway, one-way valve or other component.
142.	**Mirror, ENT, hand-held**	An instrument with a surface sufficiently polished to reflect enough undiffused light to form a virtual image of an object placed before it, for the purposes of ear/nose/throat (ENT) examinations. This mirror is mounted on a long, slender handle, and is held by the doctor who can manipulate the mirror close to the site of interest.
143.	**Mirror, ENT, headband**	An instrument with a circular concave mirror attached to a headband acting as a reflector that is used to project a beam of deflected light to a body cavity (e.g. the nose or larynx) for the purposes of ear/nose/throat (ENT) examinations. The doctor will wear this device on his head, place the reflector in front of one eye, and view the site through a small hole in the centre of the reflector.
144.	**Mirror, general or plastic surgery**	A device designed to be used to assist practitioners during general or plastic surgery that displays a virtual image of an object placed before it.
145.	**Mirror, headband, ophthalmic**	An ophthalmic instrument with a circular concave mirror attached to a headband used to project a beam of light to allow examination of the eye and its associated structures.
146.	**Orthosis, shoulder/elbow/ wrist/hand**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the shoulder, elbow, wrist and/or hand.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
147.	**Orthosis, hip/knee/ ankle/foot**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the hip, knee, ankle and/or foot. The device may be an articulated single item or a collection of compatible units specific for various parts of the leg.
148.	**Orthosis, finger**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the finger.
149.	**Orthosis, footwear insert**	A specially designed footwear insert intended to provide support for the base of the foot.
150.	**Orthosis, sacroiliac spine**	An externally applied orthopaedic appliance or apparatus that encompasses the sacroiliac spine region of the trunk and is used to support or immobilise deformities, fractures, sprains, or strains of the spine.
151.	**Orthosis, thoracic spine**	An orthopaedic corset that encompasses the thoracic spine region of the trunk and is used to support or immobilise deformities, fractures, sprains or strains of the spine through compression of the abdomen.
152.	**Orthosis, cervicothoracic spine**	An externally applied orthopaedic appliance or apparatus used to support or immobilise deformities, fractures, sprains or strains of the cervicothoracic spine.
153.	**Orthosis, cervical spine**	An externally applied orthopaedic appliance or apparatus used to support or immobilise deformities, fractures, sprains or strains of the cervical spine.
154.	**Orthosis, lumbosacral spine**	An externally applied orthopaedic appliance or apparatus that encompasses the lumbosacral spine region of the trunk and is used to support or immobilise deformities, fractures, sprains or strains of the spine.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
155.	**Paper, recording**	A device prepared from a thin sheet of fibrous material specially produced for recording the output of devices measuring physiologic parameters (e.g. electrocardiogram (ECG), electroencephalogram (EEG), or for ultrasound imaging).
156.	**Intravenous pole**	A pole or rod with 2 or more hooked bars extending horizontally from its top from which various fluid delivery devices (bags or bottles) can be suspended for the administration of intravenous (IV) fluids or medication to the patient. Commonly known as an IV pole or drip pole, it can be a fixed or side-swinging, adjustable, vertical pole attached to a bed or operating table, ceiling-mounted or, more commonly, an independent floor-standing IV pole for bedside use. It may have wheels to allow patient mobility.
157.	**Pressure alleviation pad**	A device designed to prevent pressure sores (e.g. bed sores or decubitus ulcers) occurring on the parts of the patient's body which are prone to this. It can equally be used as an underlay for the patient when he/she is undergoing a long treatment where the body is immobilised, or for disabled, infirm persons who are confined to sitting/lying positions. This device is usually constructed as an underlay but can also be formed to accommodate the patient's body shape, prominent or unprotected bony parts (e.g. as mattresses (both active and passive), pads or skins of different materials).
158.	**Finger protector**	A device intended to be used to protect an injured finger from further trauma during the healing process. It will typically be made of durable materials (e.g. plastic, rubber, reinforced metal).

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
159.	**Protector, foot**	A device designed to cover a part of the body, or to be worn over the foot to protect that part of the foot from friction against surfaces and knocks against objects. It is typically made of soft padded materials, and supplied in pre-cut sizes or shapes. It may have additional properties (e.g. waterproof, lubricating, hypoallergenic). It is typically used by persons who suffer from common foot ailments such as bunions, corns, blisters, calluses, ingrown toe nails, hammer toes, overlapping toes or spurs.
160.	**Projector, visual acuity**	An ophthalmic device, a kind of slide projector/ beamer throwing block letters or other symbols on a screen/wall in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; and used in testing visual acuity.
161.	**Prosthesis, arm, non-active**	An artificial substitute for a missing or dysfunctional arm used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
162.	**Prosthesis, ankle/foot, external, non-active**	An artificial substitute for an ankle and/or foot, or foot part, used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of a lower limb prosthetic system. This is a non-active medical device.
163.	**Prosthesis, breast, external, non-active**	An external device used to replace the breast typically after a mastectomy, intended to restore some degree of the appearance and/or function of the normal anatomy. It is made of various materials to simulate the appearance and texture of a breast and is typically fitted into a brassiere. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
164.	**Prosthesis, elbow, external, non-active**	An artificial substitute for the upper limb missing at the elbow joint used to restore some degree of the appearance and/or function of the normal anatomy. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments, or it moves as the result of a connection with another functional limb component. The position of the device may be maintained through a manual or automatic locking mechanism. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
165.	**Prosthesis, hand, non-active**	An artificial substitute for a missing hand used to restore some degree of the appearance and/or function of the normal anatomy. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments. The position of the device may be maintained through a manual or automatic locking mechanism. The device may be used as part of an upper limb prosthetic system. The device is external. This is a non-active medical device.
166.	**Prosthetic hand range-of-motion aid, non-active**	A device positioned on the arm and maintained by friction used to increase the flexion range of the elbow allowing a prosthetic hand to reach the face of the wearer. This is a non-active medical device.
167.	**Prosthesis, hip, external, non-active**	An artificial substitute for a missing hip used to restore some degree of the function of the joint. The device is used as part of a lower limb prosthetic system. This is a non-active medical device.
168.	**Prosthesis, knee, external, non-active**	An artificial substitute for a missing knee used to restore some degree of the appearance and/or function of the joint. The device is used as part of a lower limb prosthetic system. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
169.	**Prosthesis, leg, non-active**	An artificial substitute for a missing or dysfunctional leg used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of a lower limb prosthetic system. This is a non-active medical device.
170.	**Prosthesis, shoulder, external, non-active**	An artificial substitute for a missing shoulder used to restore some degree of the appearance and/or function of the joint. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
171.	**Prosthesis, wrist, external, non-active**	An artificial substitute for a missing wrist used to restore some degree of the function of the joint. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments, or it moves as the result of a connection with another functional limb component. The position of the device can be maintained by a locking mechanism that is body-powered. The device is used as part of an upper limb prosthetic system. This is a non-active medical device.
172.	**Prosthetic socket, non-active**	A device that fits over the terminal end of a residual limb (stump) and serves as an interface between the limb and prosthesis. This is a non-active medical device.
173.	**Patient restraint**	A non-rigid device, typically a strap or band made of various materials (e.g. fabric, nylon, leather, foam), used to temporarily secure the arm or leg of an adult patient to prevent injury or hazards. The device is typically wrapped around the patient's arms or feet and anchored to a fixture or furniture part (e.g. a bedrail), restricting movement of the patient and preventing the patient from interfering with treatment (e.g. removing an intravenous or urinary catheter, handling a dressed wound).
174.	**Restraint, fingers**	A device designed to restrict finger mobility and prevent potential injury.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
175.	**Restraint, body**	A device designed to secure a patient's arms to the torso to prevent self-inflicted injury.
176.	**Retainer, bandage**	A device used to stabilise, attach or fix a bandage/dressing in a desired location. This device can be a fastener/clasp (e.g. an elastic strip with opposing gripping teeth/hooks) or tubular elastic net. It is typically used on patients sensitive or allergic to adhesive tape.
177.	**Self-exam pad, breast**	A device for use as an aid in performing breast self-examination. It consists of 2 plastic sheets with liquid sealed in between and is to be placed onto the breast. It reduces friction between the fingers and breast.
178.	**Shield, eye**	A mechanical shield, usually plastic or metallic, used for protection of one or both eyes following surgery or trauma.
179.	**Shield, face**	A clear, transparent guard worn over the face/eyes to protect the healthcare worker from blood and other body fluid splashes while performing a clinical procedure.
180.	**Shield, hip**	A mechanical guard worn over the hip area to prevent against hip fractures in the event of a patient fall.
181.	**Shield, wound**	A mechanical shield that is designed to form a protective structure over a wound. It may be cage-like and will allow exposure to air and permit access to the injured area while protecting against accidental damage.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
182.	**Shield, radiation, apron**	A full-length or half-length apron-like garment intended to shield portions of the body of a patient from exposure to radiation during medical or dental procedures. Some include attached or detachable collars for neck and thyroid protection. The device typically consists of a fluid-resistant outer covering surrounding a thin sheet of lead or lead equivalent material. Those used for neutron attenuation are composed of hydrogenous materials; those used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.
183.	**Shield, radiation, bib**	A personal protective device intended to shield the chest area of a patient from unnecessary exposure to radiation from diagnostic or therapeutic medical and dental procedures. Some have either attached or detachable collars used for neck and thyroid protection. Bibs used in diagnostic X-ray and nuclear medicine typically consist of a fluid-resistant outer covering that surrounds a thin sheet of lead or lead equivalent material. Bibs used for neutron attenuation are composed of hydrogenous materials; those used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.
184.	**Shield, radiation, blanket**	A personal protective device intended to shield the selected body parts of a patient, or others, from unnecessary exposure to radiation during diagnostic or therapeutic medical or dental procedures. Radiation protection blankets used in diagnostic X-ray and nuclear medicine typically consist of a fluid-resistant outer covering that surrounds a thin sheet of lead or lead equivalent material. Blankets intended to attenuate neutrons are composed of hydrogenous materials instead of lead. Blankets used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
185.	**Shield, radiation, eye**	A personal protective device used to cover the patient's eyes and shield them from unnecessary exposure to primary and scattered radiation associated with diagnostic and therapeutic medical procedures. Eye shields can come in various shapes and are typically made of lead glass, lead or tungsten when attenuating photons, or hydrogenous materials when attenuating neutrons.
186.	**Shield, radiation, thyroid**	A radiation protection device specifically designed to shield the thyroid of a patient from unnecessary exposure to radiation from diagnostic medical and dental procedures. The thyroid shield provides an attenuating barrier between the individual's thyroid and the source of primary or scattered radiation. Structural thyroid shields may be attached to the wall, ceiling or radiation delivery device by an articulating arm that can be adjusted to shield the thyroid area of the throat. Others may be more flexible and fit over the patient's thyroid. It typically consists of a fluid-resistant outer covering that surrounds a thin sheet of lead material.
187.	**Shield, shower**	A device designed to form a protective structure to cover part of the body in order to protect these while the user is taking a bath or shower. The device is made of waterproof materials.
188.	**Anti-slip shoe, slipper, boot**	A device designed to be worn or applied to the outer sole of the shoes of an elderly person or a person with a disability to provide such person with greater grip on the surface upon which he is walking. It is typically used to assist mobility and help prevent slipping. This includes any anti-slip devices attached to the shoe, such as clips, bands or springs, that are used to help prevent slipping.
189.	**Orthotic shoe**	Orthopaedic footwear that is intended to support, align, or prevent or correct deformities of, the feet to help improve their function.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
190.	**Cast boot**	A boot-like cover for a foot enclosed in a leg cast. This device is generally equipped with a waterproof covering, an outer sole for walking, and closures for easy application and removal.
191.	**Shoe, cast**	A shoe designed to be worn over a foot/ankle that is encased in a cast, in order to protect the cast material and provide support.
192.	**Sling**	A hanging bandage or other material that is usually suspended from the body or another structure, and used to support and limit the range of motion of an injured limb during the healing period, or to support and limit the range of motion of a body in transport.
193.	**Spectacles**	An optical/ophthalmic device consisting of a spectacle frame that contains a pair of spectacle lenses (eyeglasses).
194.	**Splint**	A rigid or semi-rigid device that serves to immobilise an injured limb or body part. It is generally placed externally along the injured limb or body part. It is typically made of plastic, mouldable plastic, wood or metal.
195.	**Splint, nasal, external**	A rigid or partially rigid device intended for use externally for the immobilisation of parts of the nose typically after a fracture or treatment. It may function as a truss-like support on the outside of the nose.
196.	**Stethoscope, mechanical**	A mechanical listening device used for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening head connected by a split ''Y'' tube to the headgear with ear olives that are placed into the user's ears. Mechanical stethoscopes are typically found in 2 variants: (*a*) a general-purpose stethoscope used for clinical/ward activities; or (*b*) a reinforced stethoscope used by cardiologists.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
197.	**Cast stockinette**	A knitted, seamless tube of material, typically cotton, designed to stretch and fit any contour of the body. The device is typically used as padding under a cast or splint.
198.	**Stocking, stockinette**	A knitted, seamless tubing, typically of cotton, that is open at both ends. The device is typically used to hold bandages in place, to place uniform pressure on a leg, finger, arm or other part of an extremity, to pad the area under a cast or splint, or to cover a stump when a prosthesis is worn.
199.	**Stocking, medical support**	An elastic limb support shaped as a stocking that is worn on the upper or lower extremity to support, correct or prevent deformity, or to align body structures for functional improvement.
200.	**Stretcher**	A device on which a patient lies for transport or reclines after treatment. It may have a wheeled undercarriage, which can be foldable.
201.	**Stretcher, ambulance**	A stretcher specially adapted for use with an ambulance vehicle, including aeroplanes, helicopters or boats. It will typically have an undercarriage which folds automatically when it meets the ambulance vehicle as it is being pushed in, as well as locking devices that match up with the docking devices of the ambulance vehicle.
202.	**Stretcher, portable**	A device designed for transporting the patient from an emergency site, which is not readily accessible for standard ambulance stretchers. It can be used in mountain or marine rescue, or difficult indoor situations (e.g. narrow corridors or extremely steep stairways). It is designed to be lightweight, simple in operation and easily transported (e.g. ideally by one or 2 persons). The patient is often strapped to the device to keep him secure during transportation.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
203.	**Stretcher, bathroom**	A stretcher specially designed for the purpose of washing a patient whilst the patient lies on the stretcher. It will typically be used for patients who are disabled or incapable of supporting themselves and it may be submersed in an appropriate bath.
204.	**Reusable surgical instrument**	An instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which is intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.
205.	**Swab**	A piece of absorbent material (e.g. cotton or foam) attached to the end of a stick made of wood, plastic or wire. It is used for the application of medication or the removal of material (save for the purpose of sample collection). This is a single-use device.
206.	**Table, examination/ treatment**	A table or bed for examination and/or treatment purposes. It is typically of the construction where the patient lies upon it, i.e. as an operating table, but some may be designed so that the patient sits beside the table and is examined with instruments placed upon the table. This device can be manually operated or powered. It may be fitted with some basic functions (e.g. raise, lower or tilt) and is used in examination rooms, doctors' surgeries and minor operating rooms.
207.	**Table, instrument**	A table used for laying out sterile surgical instruments, sutures, and other utensils/items required during an operation or intervention. It is designed to include an appropriate (e.g. stainless steel) top or surface with no crevices, screws or rivets and may include telescoping pedestals for height adjustment and swivel castor bases. This table is used in the so-called ''sterile area'' of the operation site and in some cases may be attached to the operating table.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
208.	**Table, operation**	A device used to support the patient's body during surgical procedures, stabilising the patient's position and providing for optimal exposure of the surgical field. It is also designed to protect the patient from excessive manipulation, trauma and abrasion. It will typically include an appropriate top surface supported by a fixed pedestal or a movable, swivel castor base and may be divided into 3 or more hinged sections (e.g. head, body and legs) which are raised and lowered by mechanical, electro-mechanical or hydraulic systems using manual or electric controls.
209.	**Table, birthing**	An adjustable table designed to support a woman's body in an appropriate position during labour and delivery and in other examination/ treatment procedures related to pregnancy. This table will typically include leg holders, traction handles, and a receptacle for afterbirth.
210.	**Tourniquet strap**	A device that is a strip of material of uniform breadth which is applied to a limb in order to compress the arteries and regulate the blood flow. This is typically used when taking blood samples, but may be used for other purposes. It has a fastening mechanism (e.g. Velcro or a self-locking buckle) used for adjustment.
211.	**Traction unit, non-active**	A device used to apply a tensile force in order to create a distraction on body parts by means of harnesses attached to the head or pelvic area. It is non-active (static) in operation. It consists of a rigid frame with non-powered traction accessories, such as cords, pulleys or weights, and is intended to apply a therapeutic pulling force to the skeletal system.
212.	**Traction unit, non-invasive component**	A non-invasive traction device (e.g. a head halter, pelvic belt or a traction splint) that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
213.	**Transfer aid, person**	A technical aid used by attending personnel to assist in the physical transfer of a person/patient (e.g. ill, disabled or infirm) from one position to another. The device has typically no lifting capabilities and uses sliding/turning techniques. This device may be used to change the person's position, especially for those incapable of achieving this on their own, and thus prevent bedsores, or to move the person between, for example, an operating table and a bed, a wheelchair and a bath, or a chair and the toilet.
214.	**Transfer belt**	A hand-held device used by attending personnel to lift a person/patient (e.g. up from the floor onto a bed). It may be used to provide additional leverage while assisting patients in walking or in short-distance transfer activities. The device can be constructed like a carrying chair, harness, basket or lifting canvas and usually requires more than one person to operate it, thereby alleviating unnecessary strain upon each person's back.
215.	**View box, blood grouping**	A device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.
216.	**View box, diagnostic imaging, non-motorised**	A non-motorised device used to support and illuminate one or more medical images (e.g. X-ray, magnetic resonance imaging (MRI), computed tomography (CT), ultrasound or nuclear medicine) which are recorded on radiographic film (e.g. an X-ray or X-ray film) for direct viewing. This kind of radiographic view box is a simple non-motorised wall-mounted or table-mounted design. The device has a defined illumination uniformity and an attachment that is used to hold as many sheets of film in place as there is room for during viewing.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
217.	**Walking crutch**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It has one leg, a handle, and a padded platform which is placed under the armpit or forearm for support.
218.	**Walking frame, standard, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a non-wheeled frame with built-in handgrips and legs which provide support whilst walking. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.
219.	**Walking table, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a chest-height wheeled frame with a horizontal forearm support, which is pushed along using the arms and/or upper body. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.
220.	**Walking frame, wheeled, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a wheeled frame with built-in handgrips and legs which provide support whilst walking. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
221.	**Walking stick**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a wooden or metal rod with either one leg, a tripod or quadripod base (3 or 4 legs). It has a handle and/or forearm support. It can be of fixed or adjustable length and be collapsible or non-collapsible.
222.	**Wrapper, sterilisation**	A device intended to enclose medical devices that are to be sterilised. It is designed to allow sterilisation of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired.
223.	**X-ray film**	A film specifically designed for medical or dental diagnostic imaging using X-ray. It is prepared as an emulsion of light and X-ray sensitive granules on one (single-emulsion film) or both (double-emulsion film) sides of a transparent film base made of cellulose acetate, polyester resin or other appropriate material. It can basically be separated into 2 major kinds: screen and non-screen film. Screen film is sensitive primarily to the wavelengths of light emitted from image-intensifying screens. Non-screen film is designed for direct exposure to X-rays and is relatively insensitive to the visible light emitted from screens. Screen film is not limited to use with X-ray imaging systems.

".

[G.N. No. S 542/2011]

Made this 4th day of April 2012.

SERENE WEE
Acting Chairman,
Health Sciences Authority,
Singapore.

[HSA (HPRG) 401:04/01-000; AG/LLRD/SL/122D/2010/9 Vol. 1]

(To be presented to Parliament under section 72(5) of the Health Products Act).