HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

May 2014

MEDICAL DEVICE GUIDANCE

GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration

Revision 6.1

HSA
Health Sciences Authority

PREFACE

R6.1 ►This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. ◄ **R6.1**

1. INTRODUCTION

1.1. Purpose

This document provides guidance in the identification of Class A medical devices that are exempted from product registration.

1.2. Background

The Health Products Act (*Act*) and Health Products (Medical Devices) Regulations (*Regulations)* requires all medical devices, other than those exempted by the *Regulations*, to be registered with the HSA prior to placing them on the Singapore market.

Medical devices are classified into one of the four risk classes (Class A to Class D) by means of classification rules set out in GN-13: Guidance on the Risk Classification of General Medical Devices and GN-14: Risk Classification of In-Vitro Diagnostic Medical Devices. Class A represents the lowest risk medical devices and Class D represents the highest risk medical devices.

Class A medical devices supplied in a non-sterile state have been exempted from the requirement to be registered with HSA prior to being placed on the Singapore market. Hence, the product registration requirement would only be applicable to **Class A sterile, Class B, Class C and Class D** medical devices placed on the Singapore market.

Although Class A medical devices supplied in a non-sterile state have been exempted from the requirement to be registered with HSA, these medical devices shall have to conform to the Essential Principles for Safety and Performance for Medical Devices in Schedule 1 of the *Regulations* prior to their placement on the Singapore market. The duties and obligations under Part VIII of the *Act* remain applicable to dealers of such devices and the manufacture, import, supply, storage, presentation and advertisement of exempted Class A medical devices, remain under the purview of the *Act* and *Regulations*.

1.3. Scope

This guidance is applicable to all manufacturers, importers, wholesalers and Registrants of medical devices.

1.4. Definitions

Definitions that do not indicate they are set out in the Act *or Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the Act. This includes *IN VITRO* DIAGNOSTIC (IVD) PRODUCT (as set out in the *Regulations*).

REGISTRANT (as set out in the *Act*): in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the *Act*.

REUSABLE SURGICAL INSTRUMENT: 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 are intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out**.**

STERILE: means, in respect of a medical device, a state free of viable micro-organisms.

2. HOW TO USE THIS GUIDANCE

This guidance is intended to assist users in identifying their non-sterile Class A medical devices which are exempted from product registration.

This guidance document provides general guidelines and the examples of device categories provided are non-exhaustive.

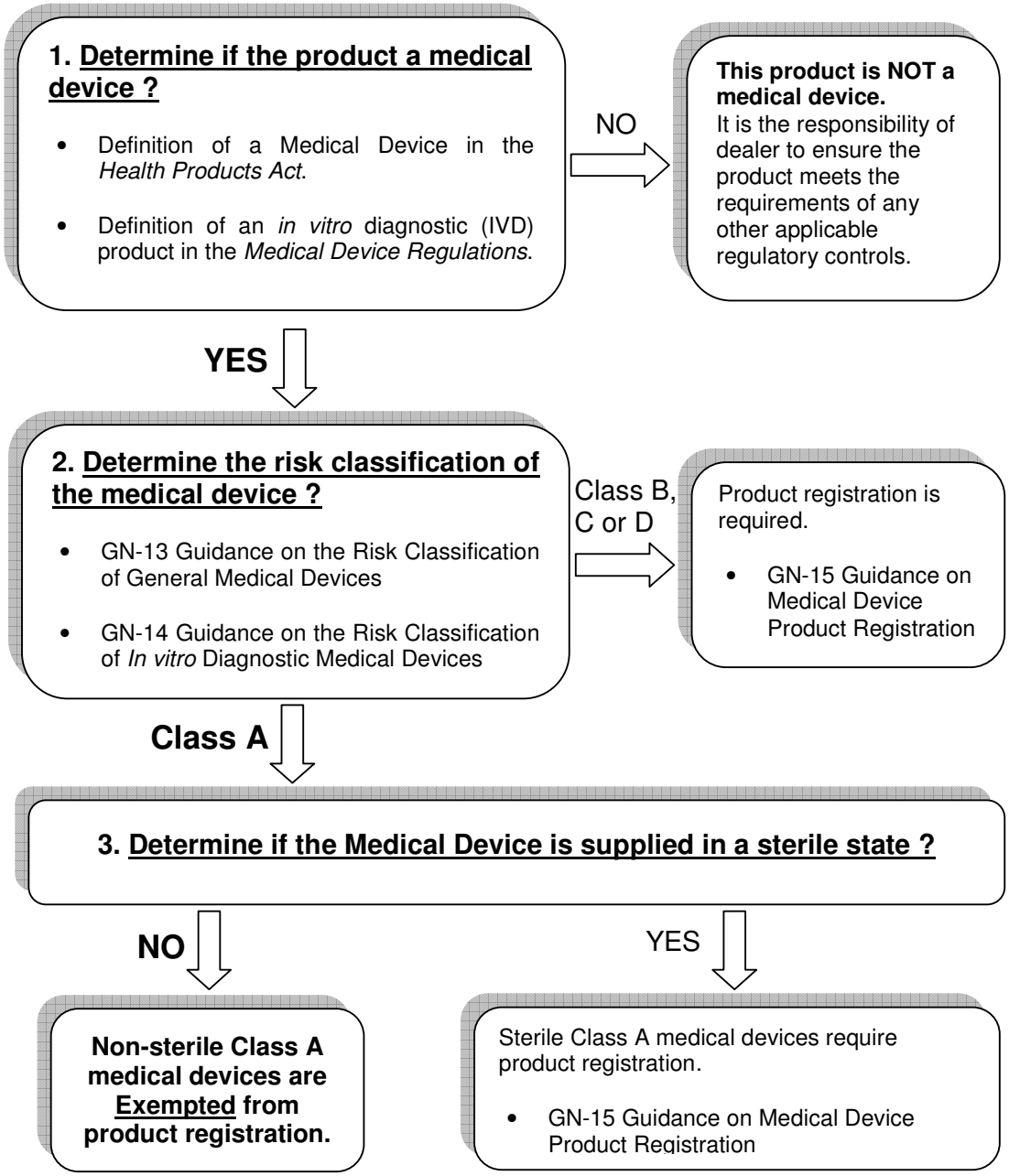
For guidance on the risk classification of medical devices, please refer to:

- GN-13 Guidance on the Risk Classification of General Medical Devices, and
- GN-14 Guidance on the Risk Classification if *In Vitro* Diagnostic Medical Devices.

Upon determination of the medical device risk classification to be Class A; the examples presented in Annex 1 of this document can then be used for reference. This annex includes a broad list of Class A device categories that have been arranged with reference to the respective risk classification rules for ease of identification.

3. CONSIDERATIONS IN DETERMINATION OF CLASS A MEDICAL DEVICES

This section provides an overview on the process of determination of a Class A medical device.



3.1. Other Points of Considerations in Identifying Class A Medical Device Exempted from Product Registration

3.1.1. Device category name and intended purposes

A generic device category name is often associated and used to describe a medical device, such as dressing, light, instrument, etc. It is to be noted that this name does not define the medical device's exact intended purpose and risk classification. The risk classification of the medical device is based on the intended purpose of the medical device. Some examples of these device categories with medical devices in different risk classes are shown below.

Example 1

Device Categories / Intended Purpose	Applicable Risk Rule	Risk Class	Require Product Registration
Adhesive bandage - to cover and protect intact skin or wounds. Intended for single-use.	**Rule 1** - All non-invasive devices which come into contact with injured skin: ....intended to be used as a mechanical barrier, for compression....Class A	**Class A**	**NO** (Exempted Class A)
Adhesive bandage, <u>sterile</u> - to cover and protect intact skin or wounds. Intended for single-use.	*As above*	Class A (Sterile)	YES
Adhesive bandage, anti-microbial, <u>sterile</u> - to cover and protect intact skin or wounds, incorporated with anti-microbial drugs. Intended for single-use.	**Rule 1** - All non-invasive devices which come into contact with injured skin: ...Unless...heal by secondary intent... Class C **Rule 13** - All devices incorporating...a medicinal product...Class D.	Class D	YES

Example 2

Device Categories / Intended Purpose	Applicable Risk Rule	Risk Class	Require Product Registration
Surgical forceps - instrument for grasping tissue. Intended to be reusable	**Rule 6** - All surgically invasive devices ... Unless they are reusable surgical instruments... ....Class A	**Class A**	**NO** (Exempted Class A)
Surgical forceps, <u>single-use, sterile</u> - instrument for grasping tissue.	**Rule 6** - All surgically invasive devices for transient use ...Class B. **Rule 7** - All surgically invasive devices for short-term use ...Class B.	Class B	YES
Electrosurgical forceps **-** instrument for coagulation of tissue and vessels. Intended to be reusable	**Rule 6** - All surgically invasive devices for transient use are in Class B. **Rule 9** - All active therapeutic devices intended to administer or exchange energy... Unless characteristics are such that they may administer or exchange energy in a potentially hazardous way, taking account of the nature, the density and site of application of the energy...Class C.	Class C	YES
Neurological forceps **-** instrument for neurological procedures, including grasping tissue.	**Rule 6** - All surgically invasive devices... Unless intended specifically for use in direct contact with the central nervous system... Class D.	Class D	YES

3.1.2. General laboratory equipment

Reagents, instruments, apparatus, equipment or systems that are intended for general laboratory applications are generally not subject to medical device controls, unless they are intended by the product owner as medical devices, including *in vitro diagnostic* (IVD) *products.* An example of general laboratory equipment would be an incubator.

Consideration: Non-sterile IVD laboratory equipment determined to be <u>Class A</u> medical devices (IVD) shall be exempted from product registration.

Consideration: IVD equipment (analysers) designed specifically and intended to be used with specific test kits would still be required to register them with the respective test kits.

3.1.3. Reusable surgical instruments

Only **non-sterile** reusable surgical instruments classified under risk Class A shall be exempted from product registration.

Consideration: Reusable surgical instruments that are Class B, C or D will remain subject to product registration.

4. DUTIES AND RESPONSIBILITIES FOR MEDICAL DEVICE DEALERS

Exemption from product registration does not exempt the dealers (companies that manufacture, import or supply by wholesale) of these medical devices from their legal duties and obligations under the *Act* and *Regulations*. Hence, they are required to keep distribution records, complaint records, report adverse events and notify the Authority of Field Safety Corrective Actions (FSCA).

Manufacturers and importers should also ensure that their exempted Class A medical device meets the requirements for safety, quality and effectiveness for its intended purpose.

4.1. Key Regulatory Responsibilities for Presentation and Advertisements of Medical Device

Dealers shall be mindful and exercise due diligence in making label claims and advertising for their products. Presentations and advertisements for the intended use of a medical device must not deviate from the Product Owners' specifications. The product owner and manufacturer shall ensure and maintain objective evidence to substantiate the intended purpose and claims of the medical device which they are responsible for, and furnish to the Authorities when requested.

The presentation and advertisements should not arouse unwarranted or unrealistic expectations of product effectiveness/performance. The information presented and claims shall not be presented in a false or misleading way.

Presentation and advertisement of medical devices should not contain:

- *False* information/descriptions concerning the medical device

- *Misleading* information that creates an erroneous impression regarding the design specification, safety, quality and efficacy or use of the device

Medical devices that are intended for professional use only should not be advertised to the general public.

All advertisements must also comply with the Singapore Code of Advertising Practice (SCAP) drawn up by the Advertising Standards Authority of Singapore.

For guidance on labelling and advertisement of medical devices, please refer to:

- GN-23 Guidance on Labelling for Medical Devices
- GN-08 Guidance on Medical Devices Advertisements and Sales Promotion of Medical Devices

4.2. Other Responsibilities for Dealers of Exempted Class A Medical Device

Although exempted Class A medical devices do not require product registration their dealers (i.e. importers, wholesalers & manufacturers) are still required to be licensed by HSA.

As part of the existing licensing requirements, manufacturers and importers are required to submit a list of their exempted Class A medical devices to HSA via MEDICS. This reporting requirement will be done on a half yearly basis for Class A medical devices being exempted from product registration.

5. INFORMATION ON CUSTOMS CLEARANCES FOR TRADERS

The HS Codes required for Customs clearances, such as through the TradeNet® System, are managed by the Singapore Customs. The HS Codes presented in Annex 1 is non-exhaustive and for trader's reference only.

In order to determine the correct HS Code for Customs declaration purposes, please contact Singapore Customs.

Non-sterile Class A medical devices are exempted from product registration. These exempted Class A medical devices under MDB controlled HS Codes are to be declared with the product code of **HSAMDX00200**.

Under TradeNet® controls, if products are controlled by another Controlling Agency, traders are to make their Customs declarations in accordance to the requirements of these prevailing agencies.

If the importer or freight forwarder is unable to find specific medical devices in these examples, please contact our MDB TradeNet office:

Telephone: (65) 6304 5857
Email: hsa_mdb_tradenet@hsa.gov.sg
Website:
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/tradenet.html

ANNEX 1

Examples of Class A Device Categories

The following lists of Class A medical device categories have been drawn-up based on the GN-13 Guidance on Risk Classification of General Medical Devices and GN-14 Guidance on Risk Classification of IVD Medical Device. These examples are non-exhaustive and serve to only provide a reference to common Class A medical devices.

Example List for Class A General Medical Devices

NOTE Medical devices examples in this list are exempted from product registration only if they are (i) Class A, and (ii) supplied non-sterile.

For the application of the risk classification rules described; please refer to GN-13 Guidance on Risk Classification of General Medical Devices

S/N	Examples of Device Categories (Non-exhaustive list)	Applicable Risk Rules	HS Codes *For Reference*
1.	Adhesive bandage, strip	Rule 1	3005 9010
2.	Adhesive tape	Rule 1	3005 1090
3.	Administration sets for gravity infusion	Rule 2; Rule 4	9018 9020
4.	Airway exchange guide	Rule 5	9018 9090
5.	Articulating paper	Rule 5	9018 9090
6.	Bags, drainage/urine collection	Rule 4	3926 9039
7.	Bandage, gauze	Rule 1	3005 9090
8.	Bandage, gauze, roller	Rule 1	3005 9020
9.	Bandage; self-adherent, clavicle, elastic, traction	Rule 4	3005 1090
10.	Binders; abdominal, ankle, breast, chest, sternum, wrist	Rule 4	6212 9091
11.	Bite block	Rule 5	6307 9090
12.	Blood pressure cuff	Rule 4	9018 9090
13.	Camera, dental, intra-oral (no diagnostic software)	Rule 5; Rule 12	9006 3000
14.	Cast cutter	Rule 12	9018 9090
15.	Chair and table, examination/treatment	Rule 4	Dentists Chair and parts there of: 9402 1010 Other Similar Chairs excluding dentists chairs: 9402 1090 Medical Surgical Dental or Veterinary Furniture incl parts there of excl chairs: 9402 9010

16.	Charger, medical equipment and battery	Rule 12	6307 9090
17.	Chart, eye; amsler grid, colour discrimination, visual acuity	Rule 4	9018 5000
18.	Compression dressing, garment	Rule 4	6212 9091
19.	Corrective back brace	Rule 4	9021 9000
20.	Cotton ball	Rule 1	3005 9090
21.	Cotton roll, general-purpose	Rule 1	3005 9090
22.	Cover, thermometer	Rule 5	3926 9039
23.	Defibrillation pads	Rule 4	9018 9090
24.	Dental dam	Rule 5	9018 4900*
25.	Dental forceps	Rule 5	9018 4900*
26.	Dental impression material	Rule 5	3407 0020
27.	Dental impression tray	Rule 5	9018 4900*
28.	Dental placers	Rule 5	9018 4900*
29.	Dental ring	Rule 5	9018 4900*
30.	Dental scaler, manual	Rule 5	9018 4900*
31.	Dental sectional matrix band	Rule 5	9018 4900*
32.	Dental teeth protector	Rule 5	9018 4900*
33.	Dental wedge	Rule 5	9018 4900*
34.	Denture liner/dental cushion	Rule 5	9018 4900*
35.	Depressor, tongue	Rule 5	6307 9090
36.	Drill guide system	Rule 6	9018 9090
37.	ECG electrodes (skin)	Rule 4	9018 9090
38.	Face barrier, resuscitation shield	Rule 4	6307 9090
39.	Gel, ultrasound, ECG	Rule 4	3006 7000
40.	Gingiva retraction cord	Rule 5	6307 9090
41.	Gloves, examination	Rule 4	4015 1100
42.	Hospital bed, general-purpose, manually-operated	Rule 4	9402 9010
43.	Hospital bed; h*ydraulically-powered, electrically-powered, etc*	Rule 12	9402 9010
44.	Hot/Cold pack	Rule 4	6307 9090
45.	Immobiliser; *wrist, ankle, elbow, arm, knee, shoulder, whole body*	Rule 4	9021 1000

46.	Inhaler spacer	Rule 2	3926 9039
47.	Irrigation kit, eye (without solution)	Rule 2; Rule 4; Rule 5	6307 9090
48.	Irrigator, nasal (without solution)	Rule 2; Rule 5	6307 9090
49.	Laryngoscope blades	Rule 5	9019 1090
50.	Leather components of orthopaedic appliances.	Rule 14	6307 9090
51.	Light, dental; *polymerisation activator, intra-oral*	Rule 5; Rule 12	9405 4091
52.	Light, examination	Rule 10; Rule 12	9405 2010
53.	Light, surgical; *operating-room*	Rule 10; Rule 12	9405 1020
54.	Light; *headlamp, headlight, headband*	Rule 10; Rule 12	9405 4091
55.	Marker, skin	Rule 4	3926 9039
56.	Mask, face	Rule 4	6307 9040
57.	Mask, resuscitation	Rule 4	6307 9090
58.	Medical display screen; *LCD monitor, television monitor, etc.*	Rule 12	9019 1010
59.	Medical film processor	Rule 12	9019 1010
60.	Microscope instrument set	Rule 6	9011 1000
61.	Mirror, dental, hand-held	Rule 5	9018 4900*
62.	Mirror; *ENT, headband, ophthalmic, mouth, general & plastic surgery*	Rule 4	9018 9090
63.	Mouth guard, preformed	Rule 5	9018 4900*
64.	Nasal aspirator, manual	Rule 5	9019 2000
65.	Operating microscopes, surgical	Rule 12	9011 1000
66.	Orthosis; *shoulder, elbow, wrist, hand, hip, knee, ankle, foot, finger, footwear insert, spine*	Rule 4	9021 1000
67.	Orthotic footwear	Rule 4	9021 1000
68.	Patient lifts and transfer aids (Powered); *transport chairs, stretchers, etc.*	Rule 12	8713 9000
69.	Patient lifts and transfer aids; *transport chairs, stretchers, etc.*	Rule 4	8713 9000
70.	Patient restraint	Rule 4	8714 2090

71.	Percussion hammer, palpator	Rule 4	6307 9090
72.	Pressure relieving mattress/ pads	Rule 4	6307 9090
73.	Projector, visual acuity	Rule 12	9019 1010
74.	Prosthesis - external; *arm, ankle, foot, elbow, hand, hip, knee, leg, shoulder, wrist*	Rule 4	Joints: 9021 3100 Other Parts of the body: 9021 3900
75.	Radiation shield; *apron, bib, blanket, eye, thyroid*	Rule 4	9022 9090
76.	Retinal camera	Rule 12	9006 3000
77.	Reusable surgical instruments (not intended to contact the central nervous system/central circulatory system)	Rule 6	9018 9090
78.	Self-exam pad, breast	Rule 4	6307 9090
79.	Shield; eye, face, hip, wound	Rule 4	63079090
80.	Sitz bath	Rule 4	6307 9090
81.	Sizer templates	Rule 6	9018 9090
82.	Sling bandage	Rule 4	9021 9000
83.	Software, image viewing and recording only	Rule 12	*Based on intended use of software*
84.	Sphygmomanometers, aneroid, mercurial	Rule 4	9019 1090
85.	Spirometer (manual)	Rule 4	9019 1090
86.	Splint	Rule 4	9021 1000
87.	Stethoscope, mechanical	Rule 4	9018 9000
88.	Stretcher; ambulance, portable, bathroom	Rule 4	8713 9000
89.	Surgical drape, general-purpose	Rule 4	6307 9090
90.	Surgical gowns	Rule 4	6211 4310
91.	Swab	Rule 4	3808 9490
92.	Syringes (without needles)	Rule 2	9018 3190/9018 3110
93.	Tourniquet strap	Rule 4	6307 9090
94.	Traction unit, non-invasive component	Rule 4	9021 1000
95.	Trial lens set	Rule 4	9001 4000
96.	Umbilical cord clamp	Rule 4	9018 9090
97.	Vaginal speculum	Rule 5	9018 9090

98.	View box, blood grouping	Rule 12	3006 2000
99.	Walking aids; *crutch, frame, table, stick*	Rule 4	6602 0000
100.	Wheelchairs (manual)	Rule 4	8713 1000
101.	Wheelchairs (powered)	Rule 12	8713 9000
102.	X-ray cassette; *digital imaging, manual*	Rule 4	9022 9090
103.	X-ray film	Rule 4	3705 9010

* controlled by another Controlling Agency

Example List for Class A *In-Vitro* Diagnostic (IVD) Devices

NOTE ***Medical devices examples in this list are exempted from product registration only if they are (i) Class A, and (ii) supplied non-sterile.***

For the application of the risk classification rules described, please refer to GN-14 Guidance on Risk Classification of IVD Medical Device

NOTE *Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD medical devices.*

S/N	Examples of Device Categories (Non-exhaustive list)	Applicable Risk Rules	HS Codes *For Reference*
1	General culture media (non-selective)	Rule 5	3821 0010 / 3821 0090
2	General laboratory equipment - intended and labelled as IVD; *centrifuges, incubators, microscope* etc.	Rule 5	9019 1010
3	Open analyzers, equipments, machines - intended for use with any brands of test kits/reagents from other product owners for IVD purpose	Rule 5	9019 1010
4	Specimen receptacles; *blood, tissues, urine, etc.*	Rule 5	3926 9039 Blood collection tubes 3006 2000

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Device Branch
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
Tel: 6866 3560
Fax: 6478 9028
Email: hsa_md_info@hsa.gov.sg

HSA
Health Sciences Authority