HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

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

Revision 6.2

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. ◄

REVISION HISTORY

Guidance Version (Publish Date)	Revision
GN-22: Revision 6 (May 2012)	R6
R6.1 ► GN-22: Revision 6.1 (May 2014)	R6.1
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**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

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 R6.2 ► by HSA licensed dealers. ◄ 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.

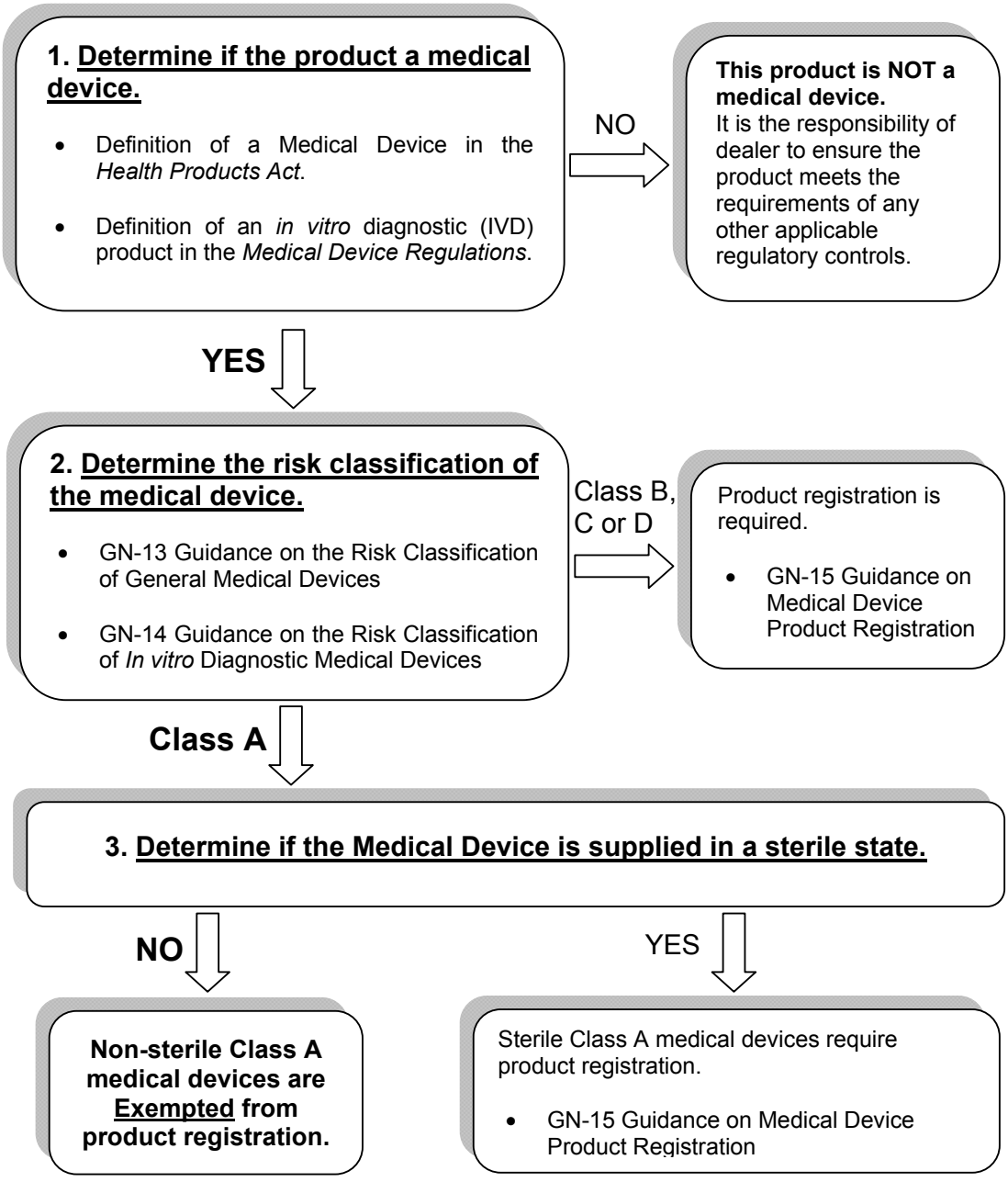
For guidance on the risk classification of medical devices, please refer to:

- 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.

R6.2 ► Some examples of common Class A devices are presented in Annex 1 of this document can be used as reference to guide user in determining the risk classification of the medical device in question. ◄ The 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, non-sterile - 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**
Adhesive bandage, sterile - to cover and protect intact skin or wounds. Intended for single-use.	*As above*	Class A	YES
Adhesive bandage, anti-microbial, sterile - 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, non-sterile - 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**
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 subjected 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 Class A medical devices (IVD) shall be exempted from product registration.

Consideration: IVD equipment (analysers) designed specifically and intended to be used with specific test kits are required to be registered with the respective test kits.

3.1.3. Reusable surgical instruments

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

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

4. DUTIES AND RESPONSIBILITIES FOR MEDICAL DEVICE DEALERS

4.1. Key Regulatory Responsibilities for Dealers of any Class A Medical Device

Although exempted Class A medical devices do not require product registration, dealers (i.e. importers, wholesalers & manufacturers) are still required to be licensed by HSA and comply with their legal duties and obligations under the *Act* and *Regulations.* Hence, dealers are required to keep distribution and complaint records, report adverse events (AE) and notify the Authority of Field Safety Corrective Actions (FSCA).

R6.2 ► FOR GUIDANCE ON MEDICAL DEVICE AE AND FSCA REPORTING, PLEASE REFER TO:

- GN-05 Guidance on the Reporting of Adverse Events for Medical Devices
- GN-10 Guidance on Medical Device Field Safety Corrective Action ◄

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.

As part of the licensing requirements, manufacturers and importers are required to submit a list of their exempted Class A medical devices electronically to HSA via MEDICS. R6.2 ► The list of exempted Class A medical devices manufactured or imported shall be up-to-date prior to the importation of these devices and shall be updated by the licensed manufacturers and importers periodically as stipulated in the licensing conditions, even if there is no update to the exempted Class A medical device list. ◄

4.2. 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

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

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

R6.2 ► Under TradeNet® controls, for products codes managed by HSA, kindly refer to our TradeNet® controls website and make the Customs declarations in accordance to the requirements of Singapore Customs. ◄

Website:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/import-declarationattradenet.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
1.	Adhesive bandage, strip	Rule 1
2.	Adhesive tape	Rule 1
3.	Administration sets for gravity infusion	Rule 2; Rule 4
4.	Airway exchange guide	Rule 5
5.	Articulating paper	Rule 5
6.	Bags, drainage/urine collection	Rule 4
7.	Bandage, gauze	Rule 1
8.	Bandage, gauze, roller	Rule 1
9.	Bandage; self-adherent, clavicle, elastic, traction	Rule 4
10.	Binders; abdominal, ankle, breast, chest, sternum, wrist	Rule 4
11.	Bite block	Rule 5
12.	Blood pressure cuff	Rule 4
13.	Camera, dental, intra-oral (no diagnostic software)	Rule 5; Rule 12
14.	Cast cutter	Rule 12
15.	Chair and table, examination/treatment	Rule 4
16.	Charger, medical equipment and battery	Rule 12
17.	Chart, eye; amsler grid, colour discrimination, visual acuity	Rule 4
18.	Compression dressing, garment	Rule 4
19.	Corrective back brace	Rule 4
20.	Cotton ball	Rule 1
21.	Cotton roll, general-purpose	Rule 1
22.	Cover, thermometer	Rule 5
23.	Defibrillation pads	Rule 4
24.	Dental dam	Rule 5
25.	Dental forceps	Rule 5

26.	Dental impression material	Rule 5
27.	Dental impression tray	Rule 5
28.	Dental placers	Rule 5
29.	Dental ring	Rule 5
30.	Dental scaler, manual	Rule 5
31.	Dental sectional matrix band	Rule 5
32.	Dental teeth protector	Rule 5
33.	Dental wedge	Rule 5
34.	Denture liner/dental cushion	Rule 5
35.	Depressor, tongue	Rule 5
36.	Drill guide system	Rule 6
37.	ECG electrodes (skin)	Rule 4
38.	Face barrier, resuscitation shield	Rule 4
39.	Gel, ultrasound, ECG	Rule 4
40.	Gingiva retraction cord	Rule 5
41.	Gloves, examination	Rule 4
42.	Hospital bed, general-purpose, manually-operated	Rule 4
43.	Hospital bed; h*ydraulically-powered, electrically-powered, etc*	Rule 12
44.	Hot/Cold pack	Rule 4
45.	Immobiliser; *wrist, ankle, elbow, arm, knee, shoulder, whole body*	Rule 4
46.	Inhaler spacer	Rule 2
47.	Irrigation kit, eye (without solution)	Rule 2; Rule 4; Rule 5
48.	Irrigator, nasal (without solution)	Rule 2; Rule 5
49.	Laryngoscope blades	Rule 5
50.	Leather components of orthopaedic appliances.	Rule 14
51.	Light, dental; *polymerisation activator, intra-oral*	Rule 5; Rule 12
52.	Light, examination	Rule 10; Rule 12
53.	Light, surgical; *operating-room*	Rule 10; Rule 12
54.	Light; *headlamp, headlight, headband*	Rule 10; Rule 12
55.	Marker, skin	Rule 4
56.	Mask, face	Rule 4

57.	Mask, resuscitation	Rule 4
58.	Medical display screen; *LCD monitor, television monitor, etc.*	Rule 12
59.	Medical film processor	Rule 12
60.	Microscope instrument set	Rule 6
61.	Mirror, dental, hand-held	Rule 5
62.	Mirror; *ENT, headband, ophthalmic, mouth, general & plastic surgery*	Rule 4
63.	Mouth guard, preformed	Rule 5
64.	Nasal aspirator, manual	Rule 5
65.	Operating microscopes, surgical	Rule 12
66.	Orthosis; *shoulder, elbow, wrist, hand, hip, knee, ankle, foot, finger, footwear insert, spine*	Rule 4
67.	Orthotic footwear	Rule 4
68.	Patient lifts and transfer aids (Powered); *transport chairs, stretchers, etc.*	Rule 12
69.	Patient lifts and transfer aids; *transport chairs, stretchers, etc.*	Rule 4
70.	Patient restraint	Rule 4
71.	Percussion hammer, palpator	Rule 4
72.	Pressure relieving mattress/ pads	Rule 4
73.	Projector, visual acuity	Rule 12
74.	Prosthesis - external; *arm, ankle, foot, elbow, hand, hip, knee, leg, shoulder, wrist*	Rule 4
75.	Radiation shield; *apron, bib, blanket, eye, thyroid*	Rule 4
76.	Retinal camera	Rule 12
77.	Reusable surgical instruments (not intended to contact the central nervous system/central circulatory system)	Rule 6
78.	Self-exam pad, breast	Rule 4
79.	Shield; eye, face, hip, wound	Rule 4
80.	Sitz bath	Rule 4
81.	Sizer templates	Rule 6

82.	Sling bandage	Rule 4
83.	Software, image viewing and recording only	Rule 12
84.	Sphygmomanometers, aneroid, mercurial	Rule 4
85.	Spirometer (manual)	Rule 4
86.	Splint	Rule 4
87.	Stethoscope, mechanical	Rule 4
88.	Stretcher; ambulance, portable, bathroom	Rule 4
89.	Surgical drape, general-purpose	Rule 4
90.	Surgical gowns	Rule 4
91.	Swab	Rule 4
92.	Syringes (without needles)	Rule 2
93.	Tourniquet strap	Rule 4
94.	Traction unit, non-invasive component	Rule 4
95.	Trial lens set	Rule 4
96.	Umbilical cord clamp	Rule 4
97.	Vaginal speculum	Rule 5
98.	View box, blood grouping	Rule 12
99.	Walking aids; *crutch, frame, table, stick*	Rule 4
100.	Wheelchairs (manual)	Rule 4
101.	Wheelchairs (powered)	Rule 12
102.	X-ray cassette; *digital imaging, manual*	Rule 4
103.	X-ray film	Rule 4

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
1	General culture media (non-selective)	Rule 5
2	General laboratory equipment - intended and labelled as IVD; *centrifuges, incubators, microscope* etc.	Rule 5
3	Open analyzers, equipments, machines - intended for use with any brands of test kits/reagents from other product owners for IVD purpose	Rule 5
4	Specimen receptacles; *blood, tissues, urine, etc.*	Rule 5

HEALTH SCIENCES AUTHORITY

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Blood Services Group
Applied Sciences Group

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