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 8

HSA
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PREFACE

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

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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 pertaining to Class A medical devices that are exempted from product registration.

1.2. Background

The Health Products Act (*Act*) and Health Products (Medical Devices) Regulations 2010 (*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 are exempted from registration with HSA prior to placement on the Singapore market. Product registration requirement is only applicable to Class B, Class C and Class D medical devices placed on the Singapore market. All medical devices shall only be manufactured, imported and wholesaled by HSA licensed dealers.

Although Class A medical devices have been exempted from the registration requirement with HSA, these medical devices shall have to conform to the Essential Principles for Safety and Performance for Medical Devices with reference to GN-16: Guidance on Essential Principles for Safety and Performance of Medical Devices and IVD Medical Devices prior to their placement on the Singapore market. Dealers are to ensure that there is a Quality Management System (QMS) in place for dealing in any Class A medical devices. For Class A medical devices supplied in a sterile state, dealers are to ensure that the sterilisation processes for any Class A sterile medical devices

conform to international standards for sterilization (such as ISO 11135, ISO 11137, ISO 17665, ISO 13408, etc) of medical devices or equivalent. 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 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: means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device, and which is intended to be reused after appropriate procedures for cleaning or sterilisation of the instrument 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 and understanding the requirements for Class A medical devices which are exempted from product registration.

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. DUTIES AND RESPONSIBILITIES FOR MEDICAL DEVICE DEALERS

3.1. Key Regulatory Responsibilities for Dealers of Class A Medical Device

Although 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).

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 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 Class A medical devices electronically to HSA via R8 ► a Product Notification application in SHARE ◄. The list of 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 regularly as stipulated in the licensing conditions.

This list of Class A medical devices submitted by R8 ► manufacturers and importers would be published on the “Class A Medical Device Database”, on the HSA website. Dealers are to ensure that information provided in the list are updated and accurate. ◄

3.2. 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 Owner's 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 evoke 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

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

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 Medical Devices

Class A General Medical Devices

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, urine	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.	Dissecting scissors	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.	Immobiliser; *wrist, ankle, elbow, arm, knee, shoulder, whole body*	Rule 4
45.	Inhaler spacer	Rule 2
46.	Irrigation kit, eye (without solution)	Rule 2; Rule 4; Rule 5
47.	Irrigator, nasal (without solution)	Rule 2; Rule 5
48.	Laryngoscope blades	Rule 5
49.	Leather components of orthopaedic appliances.	Rule 14
50.	Light, dental; *polymerisation activator, intra-oral*	Rule 5; Rule 12
51.	Light, examination	Rule 10; Rule 12
52.	Light, surgical; *operating-room*	Rule 10; Rule 12
53.	Light; *headlamp, headlight, headband*	Rule 10; Rule 12
54.	Marker, skin	Rule 4
55.	Mask, face	Rule 4
56.	Medical display screen;	Rule 12

	LCD monitor, television monitor, etc.	
57.	Medical film processor	Rule 12
58.	Mirror, dental, hand-held	Rule 5
59.	Mirror; *ENT, headband, ophthalmic, mouth, general & plastic surgery*	Rule 4
60.	Mouth guard, preformed	Rule 5
61.	Nasal aspirator, manual	Rule 5
62.	Operating microscopes, surgical	Rule 12
63.	Orthosis; *shoulder, elbow, wrist, hand, hip, knee, ankle, foot, finger, footwear insert, spine*	Rule 4
64.	Orthotic footwear	Rule 4
65.	Patient lifts and transfer aids (Powered); *transport chairs, stretchers, etc.*	Rule 12
66.	Patient lifts and transfer aids; *transport chairs, stretchers, etc.*	Rule 4
67.	Patient restraint	Rule 4
68.	Percussion hammer, palpator	Rule 4
69.	Pressure relieving mattress/ pads	Rule 4
70.	Projector, visual acuity	Rule 12
71.	Prosthesis - external; *arm, ankle, foot, elbow, hand, hip, knee, leg, shoulder, wrist*	Rule 4
72.	Radiation shield; *apron, bib, blanket, eye, thyroid*	Rule 4
73.	Reusable surgical instruments (not intended to contact the central nervous system/central circulatory system)	Rule 6
74.	Self-exam pad, breast	Rule 4
75.	Shield; eye, face, hip, wound	Rule 4
76.	Sitz bath	Rule 4
77.	Sling bandage	Rule 4
78.	Software, image viewing and recording only	Rule 12
79.	Sphygmomanometers, aneroid, mercurial	Rule 4
80.	Spirometer (manual)	Rule 4
81.	Splint	Rule 4
82.	Stethoscope, mechanical	Rule 4
83.	Stretcher; ambulance, portable, bathroom	Rule 4
84.	Surgical drape, general-purpose	Rule 4
85.	Surgical gowns	Rule 4
86.	Swab	Rule 4
87.	Syringes (without needles)	Rule 2

88.	Tourniquet strap	Rule 4
89.	Traction unit, non-invasive component	Rule 4
90.	Trial lens set	Rule 4
91.	Umbilical cord clamp	Rule 4
92.	Vaginal speculum	Rule 5
93.	View box, blood grouping	Rule 12
94.	Walking aids; *crutch, frame, table, stick*	Rule 4
95.	Wheelchairs (manual or powered)	Rule 4 or Rule 12
96.	X-ray cassette; *digital imaging, manual*	Rule 4
97.	X-ray film	Rule 4

Class A In-vitro Diagnostic Medical Device

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

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, standalone analyzers, equipment, machines - not intended for use in specific medical diagnostics purposes	Rule 5
4	Specimen receptacles; *blood, tissues, urine, etc.*	Rule 5

HEALTH SCIENCES AUTHORITY

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