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MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL GAS SYSTEM – REQUIREMENTS FOR REGISTRATION

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Regulations 2012;

b) Medical Device (Advertising) Regulations 2019; and

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:portal.mda.gov.my

MEDICAL GAS SYSTEM – REQUIREMENTS FOR REGISTRATION

0 Introduction

Medical gases are used for healthcare purposes in different ways. Some are used for treatment, some for anaesthesia, and some for driving medical devices and tools. The medical gas system (MGS) is an essential part of any healthcare facility, a failure of which can contribute to the morbidity and/or death of the patient.

Medical Gas System has inherent multiple hazards and risks to the patients, operators and person at the healthcare facility that may be associated with these devices.

It is essential that all elements such as the design, manufacturing and installation of MGS intended to be placed in Malaysian market shall meet the standards of safety, quality and performance as per the guidance.

Section 5(1) of Medical Device Act 2012 (Act 737) requires that a medical device is registered under the Act before it can be imported, exported or placed in the market. This guidance document is made pursuant to Section 5 of Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012. Only devices that comply with these requirements may be placed in the Malaysian market.

1 Scope

This guidance document specifies requirement for registration of medical gas system "placed in market" as defined in Medical Device Act 2012.

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

2.1 establishment

As defined in Section 2 of Act 737.

2.2 manufacturer

As defined in Section 2 of Act 737.

2.3 medical gas

Any gas or mixture of gases intended for the administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes.

[Source: MS 2675-1:2017]

2.4 medical gas system

A complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical and vacuum supply required.

[Source: MS 2675-1:2017]

3 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Medical Device Act 2012 (Act 737)

Medical Device Regulation 2012

MDA /GD/0009, *Rules of Classification for General Medical Devices*

MDA /GD/0007, *The Essential Principles of Safety and Performance of Medical Devices*

MDA /GD/0008, *Common Submission Dossier Template*

MDA Circular No 2/2014, *Conformity Assessment Procedures for Medical Device Approved By Recognised Countries (Appendix 1-Revision 3)*

MDA /GD/0025, *Declaration of Conformity (DoC)*

MDA /GD/0011, *Complaint Handling*

MDA /GD/0012, *Distribution Record*

MDA /GD/0013, *Field Corrective Action*

MDA /GD/0014, *Mandatory Problem Reporting*

MDA /GD/0015, *Medical Device Recall*

MDA /GD/0026, *Requirement for Labelling of Medical Devices*

MDA /GD/0020, *Change Notification for Registered Medical Device.*

MS 2675-1:2017*, Medical gas systems - Part 1: Code of practice for the design, installation, validation and verification*

4 Requirements for registration

An application for the registration of a medical device shall be made according to the requirements in Act 737 and in the manner determined by the Authority in Medical Device Regulations 2012.

Medical gas system that is intended to be placed in the market shall be registered either as a complete system, sub-system or specific/individual devices associated with the medical gas system as described in this Guidance Document.

The person responsible for registering a medical device under Act 737 is the manufacturer or the authorized representative.

4.1 Determination of grouping

There are a few categories where the manufacturer or authorized representative may register the medical gas system.

4.1.1 Category 1

The establishment may submit registration for one complete system which may include all specific/individual devices of medical gas from the source to the patient area or vice versa. The system shall come from one manufacturer and comply with the rule of grouping as per MDA/GD/0005, *Product Grouping.* The systems are as follow:

1. Oxygen System
2. Medical Air System
3. Surgical Air System
4. Nitrous Oxide System
5. Entonox (N_2O/O_2) System
6. Vacuum System
7. Anaesthetic Gas Scavenging System (AGSS)
8. Medical Gas Alarm System

4.1.2 Category 2

The establishment may submit the registration according to the sub-system/service in different area and the related specific/individual devices under that sub-system shall be listed in the list of configurations for the devices. The sub-systems are as follow:

a) Supply Sub-System:

i) Liquid Oxygen Storage System
ii)Medical Air/ Surgical Air Plant
iii)Medical Vacuum Plant
iv)Anaesthesia Gas Scavenging System
v) Automatic Changeover Manifold
vi)Manual Manifold

b) Distribution Sub-System:

i) Medical gas Pipeline
ii) Area Valve Service Unit

c) Patient Area Sub-System:

i) Gas Terminal Unit
Ii) Medical Pendant
Iii) Bedhead Panel

d) Alarm Sub-System

i) Master Alarm Panel
ii) Repeater Alarm Panel
iii) Area Alarm Panel
iv) Device Operation Panel

Example on how to fill in the List of Configurations is as per Annex E.

4.1.3 Category 3

The establishment may submit registration only for the specific/individual devices associated with the medical gas system. Examples of devices are filters, dryers, receiver, vessels etc.

For other gases such as Nitrogen, CO_2 and Helium and other individual devices, shall be registered under this category.

The list of these devices are as per Annex A.

4.2 Risk classification of devices

The classification of medical device is determined from:

(i) The manufacturer's intended purpose for the medical device,
(ii) A set of classification rules as prescribed in Medical Device Regulations 2012.

These rules will classify medical devices into one of 4 classes of medical devices, Class A, B, C and D.

The purpose of risk based classification:

(i) To make sure that the regulatory controls applied to a medical device are proportionate to risk.
(ii) To assist a manufacturer to allocate its medical device to an appropriate risk class.

The Authority shall make the final ruling upon matters of interpretation for a particular medical device.

4.2.1 Factors influencing device classification

A number of factors may influence medical device classification. These include:

a) the duration of contact of the device with the body;
b) the degree of, and site of, invasiveness into the body;
c) whether the device deliver medicines or energy to the patient;
d) whether the device is intended to have a biological effect on the body;
e) intended action on the human body;
f) local versus systemic effects;
g) whether the device comes into contact with injured skin;
h) whether for diagnosis or treatment;
i) the ability to be re-used or not; and
j) combination of devices.

4.2.2 Application rules

The class of the medical device is determined by its intended use and mechanism of action, and not the specific technical characteristics of the medical device, unless the specific technical characteristics have a direct bearing on the intended use.

If two or more rules are applicable to the medical device based on the manufacturer's intended use, the medical device is allocated the highest level of risk classification indicated.

If a medical device is intended to be used in combination with other medical device, the classification rules should be applied separately to each of the medical device.

4.2.3 Determination of medical gas system risk classification using the rule based system

The manufacturer shall:

a) determine the intended use of the medical device;

b) take into consideration all the rules that follow in order to establish the proper classification for the device, noting that where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated;

c) determine that the device is not subject to special rules resulting in different control procedures (e.g. classification into designated medical device). The classification rules with examples as attached in Annex B explains the purpose of each rule with examples.

Example 1.

When a medical device channels compressed medical gases from source to patients or through vacuum from patient to source, Rule 2 applies.

Example 2.

Pneumatic pressure source or vacuum is an active medical device, as it administers or remove energy and substances to or from the human body in a potentially hazardous way, Rule 9 and 11 apply

Manufacturer shall also refer to MDA/GD/0009, *Rules of Classification for General Medical Devices* for details on rule of classification.

The classification of other subsystem and specific/individual devices related are as specified in Annex B.

4.3 Essential Principles of Safety and Performance (EPSP).

EPSP of medical device consist of 6 general principles that apply to all medical devices and 11 principles of design and manufacturing, some of which are relevant to each medical device. In order to demonstrate the compliance of EPSP, the establishment shall submit relevant documentation/ evidence for the purpose of registration. Some examples of documentation/evidence are as follows:

- a documented and detailed risk analysis
- the results of testing of the medical device
- literature searches
- copies of the label, packaging and Instructions for Use to demonstrate that information requirements have been met
- the design dossier
- list of applicable standards used

Not all the essential principles will be applicable to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device. In determining this, account must be taken of the intended purpose of the device.

For device regulated by other authorities, the approval for that device shall be submitted together during application for registration. Examples DOSH approvals for air receivers.

Manufacturer shall also refer to MDA/GD/0007, *The Essential Principles of Safety and Performance of Medical Devices* for details on EPSP.

The checklist of EPSP are as per Annex D.

4.4 Common Submission Dossier Template (CSDT)

CSDT is used for conformity assessment and submission of application for medical device registration. The preparation of CSDT shall be made in accordance with the requirements specified in Appendix 2 of Third Schedule of Medical Device Regulation 2012 and shall be prepared by the manufacturer of the medical device.

The CSDT is the format to be used for submitting the required information of the device and as evidence of conformity of medical device to EPSP. It is considered as summary of technical documentation of the medical device. This technical documentation shall be updated as necessary to reflect the current status, specification and configuration of the device.

The CSDT shall contain all elements as specified in Appendix 2 of Third Schedule of Medical Device Regulation 2012. Where there are elements which are not applicable to the medical device, the justification for the non-applicability shall be provided.

All verification and validation testing of specific/individual devices in system/sub-system shall be compiled and submitted together with the CSDT.

Manufacturer shall also refer to MDA/GD/0008, *Common Submission Dossier Template* for the template of CSDT.

4.5 Standards for demonstrating compliance

For demonstrating compliance with the EPSP for the medical gas system, the establishment shall use MS 2675-1:2017, *Medical gas systems - Part 1: Code of practice for the design, installation, validation and verification*. Any other equivalent standards may be used to demonstrate compliance and other standards as appropriate to the relevant elements.

The list of standards is as per and not limited to the list of standards in Annex C.

4.6 Conducting conformity assessment

As per Exemption Order 2016, Class A medical devices are exempted from conformity assessment process. Medical devices under Class B, C and D shall be subjected to conformity assessment by a registered Conformity Assessment Body (CAB) before submission of registration with the Authority. In preparation to conduct conformity assessment, the manufacturer shall comply with the requirements of:

- Essential Principles of Safety and Performance of Medical Device,
- Common Submission Dossier Template (CSDT),
- Declaration of Conformity,
- Post Market Surveillance (PMS) System.

Manufacturer or Authorized Representative need to appoint a registered CAB to conduct the assessment. The CAB will issue a certificate of conformity and the report upon completion of the conformity assessment.

For medical devices that have been approved by regulatory authorities or notified bodies recognized by MDA, the element of conformity assessment shall be assessed through verification of evidence of conformity (verification process) by CAB while for medical devices manufactured locally and medical devices come from other than recognised countries, the element of conformity shall be assessed through Full Conformity Assessment route.

Manufacturer shall also refer to the following documents:

a) MDA Circular No 2/2014, *Conformity Assessment Procedures For Medical Device Approved By Recognised Countries (Appendix 1-Revision 3)*
b) MDA /GD/0025, *Declaration of Conformity (DoC)*
c) MDA /GD/0011, *Complaint Handling*
d) MDA /GD/0012, *Distribution Record*
e) MDA /GD/0013, *Fid Corrective Action*
f) MDA /GD/0014, *Mandatory Problem Reporting*
g) MDA /GD/0015, *Medical Device Recall*

5 Application Procedure

Application form for medical device registration is embedded in the MeDC@St system that can be accessed through MDA Portal. It is a web-based online application form which can be accessed via internet. To make an application, an applicant shall create a MeDC@St account.

Upon successful registration, a medical device registration certificate with unique registration number shall be issued by the Authority. The establishment shall label the devices with the registration number and other details as specified in MDA/GD/0026, *Requirement for Labelling of Medical Devices*.

Any changes to the medical device after the device is registered, the establishment shall apply for a change notification as specified in MDA/GD/0020, *Change Notification for Registered Medical Device.*

Figure 1 shows the steps to be taken to register a medical device under Act 737.

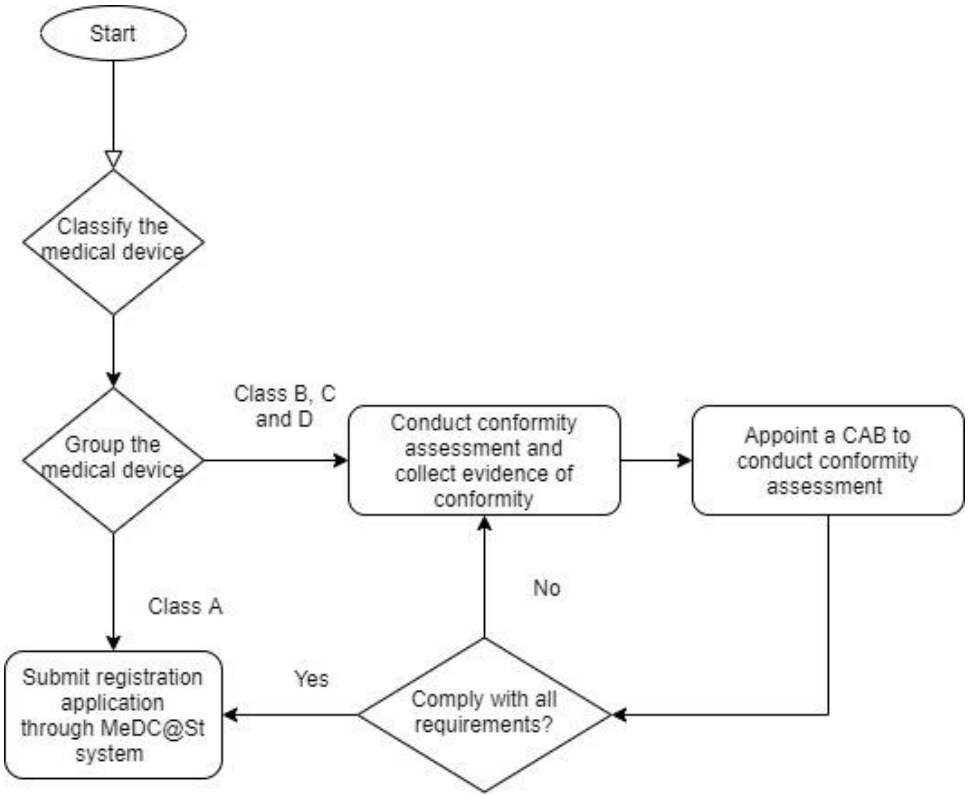

Figure 1: Steps to be taken before making an application for registration of a medical device

Annex A
(informative)

Medical Gas Sub-System and Related Individual/Specific Devices

Item(s)	Device(s)
	Supply Sub-System
1	Liquid Oxygen Storage System i) VIE Tank ii) Vaporiser System iii) Regulator for VIE System iv) Safety Valves and Bursting Disc v) Alarm system (telemetric to supplier)
2	Medical/ Surgical Air System i) Medical Grade Compressor or equivalent ii) Air Receiver iii) Medical Grade Dryer Set with Dew Point Detector iv) Filter (Oil Filter/Pre-Filter/Dust Filter/Bacteria Filter) v) Safety Valves
3	Medical Vacuum System i) Vacuum Vessel ii) Vacuum Pump iii) Bacteria Filter
4	Anaesthesia Gas Scavenging System i) Pump ii) Remote switch
5	Automatic Changeover Manifold, i) Pressure Gauge ii) Pressure Regulator iii) Pressure Switch iv) Safety Valves v) Non-Return Valve vi) Test Point vii) Solenoid Valve viii) Isolating Valve ix) Pig Tail & Header
6	Manual Manifold i) Pressure Gauge ii) Pressure Regulator iii) Pressure Switch iv) Safety Valves v) Test Point vi) Isolating Valve vii) Non-Return Valve viii) Pig Tail & Header

Distribution Sub-System	
7	Medical Gas Pipeline i) Medical Grade Pipes/Tubings ii) Fittings/Hoses iii) Valves *pipes support/sleeves/trunking are not included
8	Area Valve Service Unit
Patient Area Sub-System	
9	Gas Terminal Unit
10	Medical Pendant
11	Bed Head Panel
Alarm Sub-System	
12	Master Alarm Panel
13	Repeater Alarm Panel
14	Area Alarm Panel
15	Device Operation Panel
Individual devices	
16	Medical Gas Cylinder
17	Oxygen Concentrator (plant)

Annex B
(normative)

Classification of medical gas system

Item(s)	Device(s)	Rule	Classification
Supply Sub-System			
1	Liquid Oxygen Storage System i) VIE Tank ii) Vaporiser System iii) Regulator for VIE System iv) Safety Valves and Bursting Disc v) Alarm System (telemetric to supplier)	Rule 2, 9, 11	Class C
2	Medical/ Surgical Air System i) Medical Grade Compressor or equivalent ii) Air Receiver iii) Medical Grade Dryer Set with Dew Point Detector iv) Filter (Oil Filter/Pre-Filter/Dust Filter/Bacteria Filter) v) Safety Valves	Rule 2, 9, 11	Class C
3	Medical Vacuum System i) Vacuum Vessel ii) Vacuum Pump iii) Bacteria Filter	Rule 2, 9, 11	Class C
4	Anaesthesia Gas Scavenging System i) Pump ii) Remote Switch	Rule 2, 9,11	Class C
5	Automatic Changeover Manifold, i) Pressure Gauge ii) Pressure Regulator iii) Pressure Switch iv) Safety Valves v) Non Return Valve vi) Test Point vii) Solenoid Valve viii) Isolating Valve ix) Pig Tail & Header	Rule 2, 9, 11	Class C
6	Manual Manifold i) Pressure Gauge ii) Pressure Regulator	Rule 2, 9, 11	Class C

	iii) Pressure Switch iv) Safety Valves v) Test Point vi) Isolating Valve vii) Non-Return Valve viii)Pig Tail & Header		
Distribution Sub-System			
7	Medical Gas Pipeline i) Medical Grade Pipes/ Tubings ii) Fittings/Hoses iii)Valves *pipes support are not included	Rule 2	Class B
8	Area Valve Service Unit *including NIST Connector	Rule 2, 9, 11	Class C
Patient Area Sub-System			
9	Gas Terminal Unit	Rule 9,11	Class C
10	Medical Pendant (with terminal unit)	Rule 9,11	Class C
11	Bed Head Panel (with terminal unit)	Rule 9,11	Class C
Alarm Sub-System			
12	Master Alarm Panel	Rule 9(ii)	Class C
13	Repeater Alarm Panel	Rule 9(ii)	Class C
14	Area Alarm Panel	Rule 9(ii)	Class C
15	Device Operation Panel	Rule 9(ii)	Class C
Individual devices			
16	Gas Cylinder	Rule 2	Class B
17	Oxygen Concentrator (plant)	Rule 9,11	Class C

Annex C
(informative)

Standards of the medical gas system

Horizontal Standards		
1	MS 2675-1, *Medical gas systems - Part 1: Code of practice for the design, installation, validation and verification*	
2	MS 2675-2, *Medical gas systems - Part 2: Code of practice for operation and maintenance*	
3	ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*	
4	ISO 14971, *Medical devices - Application of risk management to medical devices*	
5	EN ISO 7396-1, *Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum*	
Vertical Standard		
Supply Sub-system		
1	Liquid Oxygen Storage System i) VIE Tank ii) Vaporiser System iii) Regulator for VIE System iv) Safety Valves and Bursting Disc v) Alarm System (telemetric to supplier)	1. ISO 4126-1, *Safety devices for protection against excessive pressure - Part 1: Safety valves* 2. EN 837-1, *Pressure gauges. Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing*
2	Medical/ Surgical Air System i) Medical Grade Compressor or equivalent ii) Air Receiver iii) Medical Grade Dryer Set with Dew Point Detector iv) Filter (Oil Filter/Pre-Filter/ Dust Filter/Bacteria Filter) v) Safety Valves	1. EN 286-1, *Simple unfired pressure vessels designed to contain air or nitrogen - Part 1: Pressure vessels for general purposes* 2. BS 3928, *Method for Sodium Flame Test from Air filters* 3. ISO 5011, *Inlet air cleaning equipment for internal combustion engines and compressors — Performance testing* 4. ISO 29463, *High-efficiency filters and filter media for removing particles in air — Part 5: Test method for filter elements* 5. ISO 8573, *The compressed air quality standard* 6. ISO 12500, *The International Standard for Compressed Air Filter Testing*
3	Medical Vacuum System i) Vacuum Vessel ii) Vacuum Pump iii) Bacteria Filter	1. BS 3928, *Method for Sodium Flame Test from Air filters* 2. ISO 5011, *Inlet air cleaning equipment for internal combustion engines and compressors — Performance testing* 3. ISO 29463-1, *High efficiency filters and filter media for removing particles from air — Part 1: Classification, performance, testing and marking*

4	Anaesthesia Gas Scavenging System i) Pump ii) Remote switch	1. ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems* 2. EN 737-2, *Medical Gas Pipeline Systems - Anaesthetic Gas Scavenging Disposal Systems - Basic Requirements* 3. EN 740, *Active Anaesthetic Gas Scavenging Pipeline System*
5	Automatic Changeover Manifold, i) Pressure Gauge ii) Pressure Regulator iii) Pressure Switch iv) Safety Valves v) Non Return Valve vi) Test Point vii) Solenoid Valve viii) Isolating Valve ix) Pig Tail & Header	1. ISO 10524-1, *Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices* 2. ISO 10524-2, *Pressure regulators for use with medical gases - Part 2: Manifold and line regulator* 3. ISO 10524-4, *Pressure regulators for use with medical gases - Part 4: Low pressure regulators*
6	Manual Manifold i) Pressure Gauge ii) Pressure Regulator iii) Pressure Switch iv) Safety Valves v) Test point vi) Isolating valve vii) Non-return valve viii)Pig Tail & Header	1. ISO 10524-1, *Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices* 2. ISO 10524-2, *Pressure regulators for use with medical gases - Part 2: Manifold and line regulators* 3. ISO 10524-4, *Pressure regulators for use with medical gases - Part 4: Low pressure regulators*
Distribution Sub-System		
7	Medical Gas Pipeline i) Pipes ii) Fittings/ Attachments iii) Safety Valves	1. EN 13348, *Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum* 2. ISO 11197, *Specifies requirements and test methods for medical supply units intended for use in healthcare facilities to supply electric power and/ medical gases and/or liquids and anaesthetic gas scavenging systems.* 3. EN 739, *Low-Pressure Hose Assemblies For Use With Medical Gases* 4. EN 1254, *Specification for Capillary Copper Fittings*
8	Area Valve Service Unit	1. EN 739, *Low-pressure hose assemblies for use with medical gases* 2. ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*
Patient Area Sub-System		
9	Gas Terminal Unit	1. ISO 9170-1, *Terminal units for medical gas pipeline systems, Part 1: Terminal units for use with compressed medical gases and vacuum*

		2. ISO 9170-2, *Terminal Units for Medical Gas Pipeline Systems, Part 2 Terminal Units for Anaesthetic Gas Scavenging Systems*
10	Medical Pendant	1. ISO 11197, *Medical Supply Units* 2. EN 793, *Particular* requirements for safety of medical supply units
11	Bed Head Panel	1. ISO 11197, *Medical Supply Units* 2. EN 793, *Particular requirements for safety of medical supply units*
Alarm Sub-System		
12	Master Alarm Panel	1. IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices* *2.* IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
13	Repeater Alarm Panel	
14	Area Alarm Panel	
15	Device Operation Panel	
Individual devices		
16	Medical Gas Cylinder	ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*
17	Oxygen Concentrator (plant)	ISO 10083, *Oxygen concentrator supply systems for use with medical gas pipeline system*

Annex D
(informative)

EPSP Checklist

EP Checklist control number:

Device Owner Name:

Device Name:

No.	Essential principles of safety and performance of medical devices	Applicable to the device? N/A	Method of Conformity/ Relevant Standards	Identity of Specific Documents / Procedure/ Report
1.	**General requirements**			
1.1	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
1.2	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer			

	should apply the following principles in the priority order listed: a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; b) eliminate risks as far as reasonably practicable through inherently safe design and manufacture; c) reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms; d) inform users of any residual risks.			
1.3	Devices shall achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.			
1.4	The characteristics and performances referred to in Clauses 6.1.1, 6.1.2 and 6.1.3 shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.			
1.5	The devices shall be designed, manufactured and packed in such a way that their characteristics and			

	performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.			
1.6	The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
2.	**Design and manufacturing principles**			
2.1	**Chemical, physical and biological properties**			
2.1.1	The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 6.1.1 to 6.1.6 of the 'General Principles'. Particular attention should be paid to: (a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability; (b) the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device; (c) the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
2.1.2	The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular			

	attention should be paid to tissues exposed and to the duration and frequency of exposure.			
2.1.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
2.1.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.			
2.1.5	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.			
2.1.6	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of			

	substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
2.2	**Infection and microbial contamination.**			
2.2.1	The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: a) allow easy handling; and, where necessary: b) reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use; c) prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.			
2.2.2	Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
2.2.3	In some jurisdictions products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to			

	veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
2.2.4	In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
2.2.5	Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
2.2.6	Devices delivered in a sterile state should be designed, manufactured and			

	packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.			
2.2.7	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
2.2.8	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
2.2.9	Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.			
2.2.10	The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
2.3	**Manufacturing and environmental properties**			
2.3.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices.			

	Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			
2.3.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and accelerations; c) the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; d) the risks of accidental penetration of substances into the device; e) the risk of incorrect identification of specimens; f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			

2.3.3	Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
2.3.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
2.4	**Devices with a diagnostic or measuring function.**			
2.4.1	Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.			
2.4.2	Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular, the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
2.4.3	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators			

	and/or control materials should be assured through a quality management system.			
2.4.4	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
2.4.5	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.			
2.5	**Protection against radiation**			
2.5.1	Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purpose.			
2.5.2	<u>Intended radiation</u> Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted,			

	where practicable, with visual displays and/or audible warnings of such emissions.			
2.5.3	Unintended radiation Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
2.5.4	Instructions for use The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
2.5.5	Ionizing radiation Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use. Device emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable			

	monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
2.6	**Requirements for medical devices connected to or equipped with an energy source**			
2.6.1	Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
2.6.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
2.6.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure,			
2.6.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.			
2.6.5	Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or			

	other devices or equipment in the usual environment.			
2.6.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
2.6.7	Protection against electrical risks: Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.			
2.7	**Protection against mechanical risks**			
2.7.1	Device should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			
2.7.2	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			
2.7.3	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise			

	emitted is part of the specified performance.			
2.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.			
2.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
2.8	**Protection against the risks posed to the patient by supplied energy or substances**			
2.8.1	Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
2.8.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
2.8.3	The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be			

	understandable to the user and, as appropriate, the patient.			
2.9	**Protection against the risks posed to the patient for devices for self-testing or self-administration**			
2.9.1	Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.			
2.9.2	Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
2.9.3	Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, which the product will perform as intended by the manufacturer.			
2.10	**Information supplied by manufacturer**			
2.10.1	Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.			
	NOTE 1. The requirements on this are addressed in the Sixth Schedule of the Medical Device Regulation.			

2.11	**Performance evaluation including where appropriate, clinical evaluation.**			
2.11.1	All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.			
2.11.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.			
	NOTE 2. Refer to the Third Schedule of Medical Device Regulation on Conformity Assessment Procedure and MDA/GD-xx: Clinical Evaluation on Medical Device for further information on the use of clinical evaluation to demonstrate compliance with these Essential Principles. This guidance document is in development process.			

Annex E
(informative)

List of Configuration Template

Example on how to fill in the List of Configuration in the application system is as below:

	Name as per Device / Constituent Components, Accessories, Reagent or Articles As Per Product Label	Permissible Variant	Details on Permissible Variant	Identifier	Brief Description of Item
1	Medical Air Plant (Double Compressor)	-	-	B- 234	Medical Air Plant with double compressors, at a flow rate determined by the site.
	Associated Devices:				
2	Compressor	-	-	Co987	Compact Medical Compressed Air Central Station according to ISO 7396-1 Class 1.4.1 with 1 oil free piston compressor belt driven ,2 electromagnetic inlet valves, 1 vessel 270lt
3	Air Receiver	Volume	Variant from 50 – 1500 L	ARX32	to store compressed air before it enters into the piping system and or equipment
4	Dryer System	-	-	Dry54	The dryer module consists of two duplex absorber towers containing activated alumina desiccant which reduces water vapour content to less than 1.0 gm/m3.
5	Control panel	-	-	CP3221	Control panel consist indicator and alarm system to monitor medical air plant

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.portal.mda.gov.my