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MEDICAL DEVICE GUIDANCE DOCUMENT

SPECIAL ACCESS – REQUIREMENTS FOR VENTILATOR DURING EMERGENCY SITUATION

In lieu of the rise of the emergency situation where the Covid-19 pandemic has occurred, the Medical Device Authority (MDA) has published this guidance document without seeking public comment as per the usual practice. This is to enable the guidance document to be published in the shortest possible period. MDA will not seek public comment prior to implementing a guidance document if the Authority determines that prior public participation is not feasible or appropriate.

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 Exemption Order 2016

b) Medical Device (Duties and Obligation 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

SPECIAL ACCESS – REQUIREMENTS FOR VENTILATOR DURING EMERGENCY SITUATION

0 Introduction

Importation and placement of a medical device in the Malaysian market requires the device to comply with the requirements of the Medical Device Act 2012 (Act 737), and the medical device shall be registered with the Medical Device Authority (MDA). The Medical Device (Exemption) Order 2016 however has provided for exemption from registration requirements of certain medical devices through special access if they fulfill the criteria and submit a notification to the Authority.

The rise of the emergency situation where the Covid-19 pandemic has occurred entails for the development of this guidance document. This is to ensure the availability of ventilators in healthcare facilities, to minimise a disruption of treatments during an emergency situation such as during the Covid-19 pandemic period.

Subsequent to the receipt of notification from the applicant, an Acknowledgement on Notification will be issued by the Authority for the purpose of importation and placement of the special access medical device after assessment of the specification by an Expet Advisory Committee established by the Authority.

This Guidance Document is used as a reference for the user, Healthcare Insitutions and Government Departments on special access applications for ventilators. Through the Expert Advisory Committee and based on the requirements of this Guidance Document, a recommendation on the suitability of the medical device to be granted special access will be provided. The user/healthcare institution/government department will make their decision based on the recommendation or otherwise, depending on their need and be responsible on the use of the MD during the emergency period.

1 Scope and application

This document specifies requirements for the importation and placing in the market of ventilators during an emergency situation through special access notification.

This Guidance document shall be read together with and MDA Circular No. 2 Year 2014, *Conformity assessment procedures for medical devices approved by recognised countries*.

2 Terms and definitions

For the purposes of this document, the terms and definitions in ACT 737, the regulations under it, the Exemption Order 2016 and the following terms and definitions apply.

2.1 emergency

An emergency is a situation that poses an immediate risk to a patient's life or long term health.

2.2 foreign regulatory authorities

Authorities that regulate medical devices in coutries outside Malaysia.

2.3 government healthcare facility

Any facility used or intended for use to provide established healthcare services, maintained, operated or provided by the Government but excluding government healthcare facilities privatized or incorporated;

[Source: Private Healthcare Facilities and Services Act (PHFSA), Act 586 1998]

2.4 healthcare facility

Any premise in which one or more members of the public receive healthcare services, which includes:

a) medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other services provided by healthcare professionals;

b) accommodation for the purpose of healthcare services provided;

c) any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind and body;

d) any service for preventive and promotion of health purpose;

e) any service provided by any healthcare para-professional;

f) any service for curing or alleviating abnormal conditions of the human body by theapplication of any apparatus, equipment, instrument or device or any other medical technology; or

g) any health-related services.

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

2.5 private healthcare facility

Any premise, used or intended for use in providing services healthcare or services related to health, such as hospital, hospice, ambulatory care center, home nursing care, maternity home, psychiatric hospital, home psychiatric care, community mental health centers, centers hemodialysis, medical clinics, private dental clinics and anything else healthcare premises or health-related premises other than as may be determined by the Minister from time to time by notification in the Gazette;

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

2.6 special access medical device

Medical device for the use of medical practitioners in emergency situations or in the event that conventional medical treatment has failed, is unavailable or unsuitable.

[Source: Medical Device (Exemption) Order 2016]

2.7 user

a person using or operating a medical device on any person acquiring services in a healthcare facility or other facilities.

3 Requirements

3.1 Eligibility

Unregistered medical devices that are to be imported and/or placed in the Malaysian market may only apply for special access only during emergency situations in the event that conventional medical treatment has failed, is unavailable or unsuitable, and when there is a need by Healthcare Institutions.

Note. Place in the market means to make available a mediacal device in return for payment or free of charge with a view to distributing, using, supplying or putting into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device.

Ventilators that are eligible for special access are also subject to the following criteria.

Table 1. Eligibility criteria

Criteria no.	Eligibility
1	Ventilators approved/registered by recognised countries (US, EU, Japan, Australia, Canada)
2	• Ventilators approved/registered by foreign regulatory authorities or through emergency situation requirements. • Ventilators manufactured locally.

4 Notification procedure

An applicant who wishes to import and/or places ventilator in the Malaysian market through special access route shall notify the Authority.

a) The applicant shall submit the notification form together with required information/ documents as described in Table 3 to the Chief Executive of Medical Device Authority (MDA) by email at sa.cm@mda.gov.my.

b) The form for 'Notification of Medical Devices for Special Access (Route A)' can be downloaded from the Authority website at www.mda.gov.my.

c) One notification application shall be made for only one single medical device or one medical device grouping.

d) The applicant may proceed to import and/or place the medical device in Malaysian market only after receiving the acknowledgment on notification from the Authority (refer flowchart in Annex C).

Table 3. Notification form particulars

No.	Particular	Explanation
Section A: Details of Applicant/Company		
1.	Category of Applicant	Tick the category of applicant as applicable
2.	Name of Applicant	Full name of applicant as per NRIC/Passport
3.	NRIC/Passport Number	State NRIC for Malaysian or Passport Number for foreign citizen
4.	Designation	State designation of applicant in the organisation.
5.	Name & Address of Organization	The name and address of organisation of applicant.
6.	Telephone No.	Please state telephone number of applicant.
7.	Email Address	Please state email address of applicant.
8.	Does the company already hold Establishment License	If Yes, please state Establishment License number under Act 737 and please tick the role of company in accordance with establishment license issued by MDA. If No, please proceed to Section B
Section B: Details of Medical Practitioner/Healthcare Institution/Government Department (where applicable)		
1.	Name of responsible person	Please state the name of medical practitioner/responsible person of Healthcare Institution/Government Department who is responsible for the importation and/or placement of the medical device in the Malaysian market or requires the use of the medical device (where applicable).
2.	Title	Please state the title of the medical practitioner/responsible person.
3.	Annual Practicing Certificate Number	Please state the Annual Practicing Certificate Number issued by Malaysian Medical Council (if applicable).
4.	Telephone No.	Please state telephone number of medical practitioner/person responsible.
5.	Email Address	Please state email address of medical practitioner/person responsible.
6.	Health Care Facility(ies) Name & Address	Please state the name and address of healthcare facility(ies) at which the device is to be used. State full name of healthcare facility.
Section C: Details of Medical Device (Appendix I)		
1.	Name of Medical Device	Please state name of the medical device, brand/model as per written in the labels, IFU, brochures, etc.
2.	Grouping	Please select grouping that is applicable to medical device. The grouping should be done accordance with Rules of grouping as specified in the Second Schedule of the Medical Device Regulation (MDR) 2012 and further elaborated in guidance document on Product Grouping MDA/GD/0005.
3.	Brief Description	Please provide description of medical device.
4.	Brand	Please state brand/model of medical device.
5.	Identifier (catalogue or model number):	Please state identifier of the medical device.
6.	Intended use of the device	Please provide the intended use of the medical device.
7.	Manufacturer's Information	Please state name of manufacturer, contact details, address, telephone number and email address.
8.	Risk based classification	Please state risk class and rule of classification of medical device based on: • First Schedule MDR 2012;
9.	Classification Rule	

		• MDA/GD/0001 In-Vitro Diagnostic (IVD) Medical Device Classification System; or MDA/GD/0009 Rules of Classification for General Medical Devices.
10.	Quantity to be imported	Please state the quantity of the medical device to be imported into Malaysia.
11.	Marketing Approval Status in other country(-ies)	Please state the name (s) of country (ies) and provide evidence such as Declaration of Conformity /Device Licence /Registration Certificate/ 510k/etc), if applicable.
12.	List of configuration (for products in a grouping)	For medical device in a grouping, please state the name of device, accessories, constituent components, or articles.
Documents to be submitted		
1.	Documents to be submitted	• List of configuration of the medical device (for grouped devices), if applicable. • Brochure, catalogue, label, sample of device, if applicable. • Approval certificates from other countries / notified bodies, if applicable. • safety and performance validation/evidences (as according to standards), certificates, test reports, bibliographic evidences, where relevant.
Section D: Clinical Judgement/Public Health Emergency Outbreak		
• In case of an individual patient, describe the patient condition, and emergency treatment requiring the device. • In case of public health emergency, prescribe the outbreak requiring the device.		
Section E : Medical Device Safety Information		
1.	List the registered devices	List the currently available registered devices that are normally used for treatment or diagnosis in the emergency procedure and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient (if available).
2.	Summarize the known safety and effectiveness information in respect of the device.	Please summarise the benefit of the device.
3.	Batch release	For batch release please provide the number of the devices required for one month. i.e. outbreak situation
SECTION F : Undertaking of Medical Practitioner		
Medical practitioner are required to make an undertaking that they will inform the patient/ next of kin of the risks and benefits associated with the use of the device. It shall be signed by medical practitioner. It shall include signature, name, date and healthcare facility stamp.		
Section G : Attestations & Declaration		
i.	Signature	Attestation to be signed by medical practitioner/ person responsible for this application. Criteria for person responsible: a) Shall be from top management; i. Person responsible shall have the overall control and have the authority to make decision; ii. Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager.
ii.	Name	
iii.	Designation	
iv.	Date	
v.	Company stamps	

4.1 Notification routes and requirements

Table 2 provides the notification requirements for the respective criteria.

Table 2: Requirements as according to the notification routes

Citeria no.	Requirements
1	a) The applicant shall ensure ventilator is manufactured and fulfil preferred technical requirements as per Clause 5. b) The applicant/establishment shall submit the certificate/letter of approval from recognised regulatory authorities (please also refer to MDA Circular No. 2 Year 2014, *Conformity assessment procedures for medical devices approved by recognised countries*). c) The PMSV reports on any incidents or recall for the last 3 years (if applicable). d) Letter of authorisation from foreign manufacturer or establishment. e) Attestation and declaration signed by the applicant/establishment (refer Annex A, Section G).
2	a) The applicant shall ensure ventilator is manufactured and fulfil minimum technical requirements as per Clause 5. b) The applicant/establishment shall submit the approval certificate from foreign regulatory authorities/ letter of approval during emergency period from regulatory authorities. c) Letter of authorisation from foreign manufacturer or establishment. d) Attestation and declaration signed by the applicant/establishment (refer Annex A, Section G). e) For locally manufactured ventilators, the manufacturers shall establish Standard Operating Procedures on its manufacturing process and shall obtain certification to ISO 13485 withinn 1 year period from end of the emergency period.

4.2 Conditions for acknowledgement on special access

4.2.1 Conditions for Criteria No. 1:

a) The applicant/establishment shall be responsible for establishing and implementing a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident with regards to the use of these ventilators. The applicants/establishment shall maintain the distribution record and traceability.

b) To continue placing of the medical devices in the Malaysian market, the applicant/establishment shall apply for medical device registration and license under the Act 737 once Malaysia is free from the emergency situation.

c) The user/healthcare institution shall be responsible on the use of the device if the devices continued to be used without registration with the Authority (refer MDA/GD/0053 on Oprhaned medical device and MDA/GD/0055 on Obsolete and discontinued medical device.

4.2.2 Conditions for Criteria No. 2:

a) The applicant/establishment shall be responsible for establishing and implementing a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident with regards to the use of these ventilators. The applicants/establishment shall maintain the distribution record and traceability;

b) For locally manufactured ventilators, the manufacturers shall establish Standard Operating Procedures on its manufacturing process and shall obtain certification to ISO 13485 withinn 1 year period from end of the emergency period.

c) To continue placing of the medical devices in the Malaysian market, the applicant/establishment shall apply for medical device registration and license under the Act 737 once Malaysia is free from the emergency situation.

d) The user/healthcare institution shall be responsible on the use of the device if the devices continued to be used without registration with the Authority (refer MDA/GD/0053 on Oprhaned medical device and MDA/GD/0055 on Obsolete and discontinued medical device).

5 Preferred technical requirements

Specification	Description
Quality Management System	Manufacturer shall establish and maintain ISO 13485 certification.
Basic requirements	To provide various modes of ventilatory support in critical care areas for infants, paediatrics and adult patients.
Ventilatory modes shall include	a) Control/ Assist Control/ Continuous Mandatory Ventilation (CMV) b) Synchronized Intermittent Mandatory Ventilation (SIMV) c) Pressure Support (PS) d) Continuous Positive Airway Pressure (CPAP) or equivalent e) Pressure Control Ventilation (PCV)

Specification	Description
	f) Volume Control Ventilation (VCV) with option of constant and decelerating flow g) Pressure Regulated Volume Control or equivalent h) Airway Pressure Release Ventilation (APRV)/Bi-Level/ BIPAP or equivalent i) Non Invasive Positive Pressure Ventilation (NIPPV) with leak compensation
Operator set variables shall include at least	a) Tidal Volume of at least 10-1500mls b) CMV breath rate 0-80/min c) SIMV breath rate 0-40/min d) Peak Inspiratory Pressure 5 – 100 cmH_2O e) Peak inspiratory flow i. Min flow 1L/min ii. Max flow not less than 140 L/min f) Inspiratory time: Expiratory time ratio g) Inspired oxygen concentration (FiO_2) of 21% - 100% h) Trigger sensitivity shall include both flow and pressure trigger i) Positive End Expiratory Pressure up to at least 40 cmH_2O j) Pressure Support in the range 0 to 60 cmH_20
For non-invasive ventilation (NIPPV) the following features shall be available:	a) Shall automatically compensate for leakage through mask – vendor to specify the value. b) Inspiratory Pressure of at least 50 cmH_2O c) CPAP of up to 25 cmH_2O d) Set Respiratory Rate from 1 to 50 bpm e) Apnea backup to be available
Display of the parameters	a) All set and delivered parameters shall be stated in offer letter. b) Fully integrated display panel of set and delivered parameters on a single LCD touch screen of at least 12 inches in size.

Specification	Description
Parameters to be shown - breath by breath monitoring display of the following data	a) Expired Tidal Volume b) Expired Minute Volume c) Spontaneous Minute Volume d) Breath Rate e) Inspiratory: Expiratory time f) Inspired Oxygen Concentration g) Peak Airway Pressure h) Mean Airway Pressure i) Plateau Pressure j) Pressure Support level k) CPAP Level l) PEEP Level m) Peak Inspiratory Flow n) Wave Forms and Flow Patterns o) Rapid Shallow Breathing Index or equivalent
Respiratory maneuvers - measured parameters should be clearly displayed.	a) Inspiratory Hold b) Expiratory Hold c) P 0.1 or Equivalent d) Negative Inspiratory Pressure or equivalent
Ventilator alarm functions	a) Audible alarm with different colour intensity b) High Airway Pressure c) Low/ High Expired Minute Volume d) Low/ High Tidal Volume e) Apnea alarm with backup ventilation f) Low/ High End Expiratory Pressure g) High continuous pressure h) Oxygen concentration (FiO_2) i) Gas/power supply failure

Specification	Description
	j) Disconnection k) Loss of PEEP l) Technical error
Essential Component	a) Heavy duty compressor or equivalent (optional) b) Internal battery at least 3 hours of ventilation for emergency backup in case of an electrical power supply failure c) High quality mobile pedestal mounted on high quality castor d) Hinged support arm with circuit support 'Y' e) Colour coded gas hoses with water traps and appropriate pipelineprobes, minimum length of 4 m. f) Breathing circuits – reusable and autoclave (silicone material)-including water traps and y piece (with temperature probe port) i. Two sets each of adult and paediatric circuit ii. Disposable circuit for adult x 100 sets/unit iii. Disposable circuit for pediatric x 20 sets/unit g) Disposable bacterial and viral filters at inspiratory and expiratory each limbs (consumables depend on needs of hospital). h) Humidifier: i. Hot water heater/bath variety servo controlled. ii. Adjustable inspired gas temperature iii. Airway temperature digital display iv. High and low temperature alarm v. Autoclavable chamber/housing heater hose chamber vi. Hose heating wire in the inspiratory limb
Power requirements	a) 240V/50-60 Hz with battery back up b) Driving gas compressed air at 50-60 psi/ Oxygen 50-60 psi c) The power supply shall comply with the Malaysian requirements, rules and regulations.

Specification	Description
Standard accessories	a) Accessories necessary to complete a fully functional system should be supplied. b) Inclusive of stand-alone ultrasonic nebulizer.
Safety	a) The machine comes with over pressure valve b) The machine comes with active exhalation valve c) Vendor to specify others d) All equipment supplied shall in all relevant respects conform to the current editions of all relevant Malaysian Standards or International Standards with regards to the design, construction, performance and tests. e) Where applicable, the vendor shall submit copies of all relevant and pertinent test reports on safety and efficacy (including IEC 60601 test report). List of standards specific to ventilator is as per in Annex D.
Infection control parts	a) All parts coming into contact with the patient's breath shall be either disposable or decontaminatable between patients. b) All external surfaces shall be cleanable in the likely event that they get respiratory secretions or blood splatter on them. c) There shall be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need to be accounted for with some designs.
Support, training & maintenance	a) Adequate clinical on-site training by competent personnel shall be provided to the user. b) Information on warranty, technical support and maintenance shall be provided to the user. c) The user manual shall be provided with the device.

PART II

6 Off-label use

By definition, off-label use is an act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer.

In conjuction with an emergency situation, there are significant concern regarding the availability and supply of ventilators in healthcare institution. Therefore, Medical Device Authority has considered ways to meet potential needs. One of the possible ways brought forward to the attention of the Authority was allowing the conversion of anaesthesia machines into ventilators.

The Authority strongly encourage healthcare facilities to use conventional/standard full-featured ventilators registered with the Authority when available to support patients with respiratory failure.

To facilitate the healthcare needs, and to overcome the global supply shortage of ventilators, manufacturers may make certain modifications to approved indications, claims, or functionality of these devices, without prior submission of a premarket approval where the modification will not create an undue risk in light of the public health emergency. In such circumstances, the Authority recommends that the manufacturer provide clear instructions delineating approved indications and claims from those that are not, in addition to a general statement about changes that have not been subject for pre-market approval.

Health care providers should use their judgment based on the condition of the patient and the circumstances in the facility to choose the best option. Examples of alternative uses of respiratory devices used to address shortages might include the following, which may help increase availability:

a) For any patient needing ventilatory support, continuous ventilators labeled for home use may be used in a medical facility setting depending on the features of the ventilator and provided there is appropriate monitoring (as available) of the patient's condition.

b) For stable patients, emergency transport ventilators may be used for prolonged ventilation in a medical facility setting.

c) Noninvasive Ventilation (NIV) Patient Interfaces capable of prescribed breath may be used for patients requiring such ventilatory support, including NIV Patient Interfaces labeled for sleep apnea.

d) Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bilevel positive airway pressure (BiPAP or BPAP) machines typically used for treatment of sleep apnea (either in the home or facility setting) may be used to support patients with respiratory insufficiency provided appropriate monitoring (as available) and patient condition.

e) For any patient needing ventilatory support, anesthesia units capable of providing controlled ventilation or assisted ventilation may be used outside of the traditional use for anesthetic indication. Because of significant differences between the anesthesia units and traditional critical care ventilators, use or supervision by an anesthesia provider is recommended. Manufacturers need to provide specific instructions on safe use of anesthesia units for this indication.

6.1 Specific requirements for use of anaesthesia units as emergency ventilators

6.1.1 Before healthcare facilities consider to use the anaesthesia units as a ventilator for treating Covid-19 patients for example, they shall consider the following requirements:

a) Healthcare institution may use of anaesthesia units as a last resort, or when there are no other alternative ways to save the critical patients;

b) Only anaesthesia units that have been registered in Malaysia or approved/registered by recognised countries (US, EU, Japan, Australia, Canada) may qualify for use as ventilators.

c) Manufacturer or authorised representative has provided clear and specific instructions on the use of anaesthesia units for ventilation purposes;

d) appropriate training has been provided by manufacturer device application/technical specialist; and

e) Manufacturer or authorised representative shall work closely with healthcare institution.

f) Take appropriate precautions with environmental control (for example, negative pressure) or additional filtration where feasible: Ventilating patients with communicable diseases using devices that are single limb or noninvasive without a filtered seal from atmosphere may contaminate the room air and increase risk of transmission. This risk may be exacerbated by high-flow nasal cannula systems or CPAP machines.

g) Manufacturer shall carry out verification and validation of the modification process and provide the report to the Authority in its application for special access.

h) Healhcare practitioner shall provide necessary information on the purpose and risk associated with the use of anaesthetic units as ventilators to the patient, including and not limited to the following:

   i. that the Authority has given special access authorisation for use of the device;
   ii. of the significant known and potential benefits and risks of the emergency use of the device;
   iii. of the extent to which such benefit and risks are unknown; and
   iv. of the option to accept or refuse use of the device, of the consequence, if any, of refusing administration of the device; and of the alternatives to the device that are available and of their benefits and risks.

6.1.2 For the purpose of 7 e), the manufacturer/ its authorised representative shall:

a) submit a notification together with required information/ documents using the form in Annex B to the Chief Executive of Medical Device Authority (MDA) by email at sa.cm@mda.gov.my .

b) Provide a risk assessement report, to ensure the modification will not create an undue risk in light of the public health emergency.

c) Provide the user/ healthcare institution with appropriate documentations, procedures /instructions, trainings, and close support and monitoring associated with the use of the medical device.

d) Manufacturers shall document changes to their device in their device master record and change control records and make this information available to the Authority, if requested.

e) Manufacturers/ AR shall provide maintenance support and maintain spare parts availability for the modified units during the emergency period.

f) Manufacturer to provide appropriate labeling that helps users better understand the device modifications such as:

   i. A clear description of the device's new indications, claims, or functions, and information on the device's performance and potential risks.

   ii. Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling highlight the differences in design compared to the unmodified, registered version of the device, along with instructions for mitigating any known risks associated with these differences.

   iii. A clear distinction delineating approved indications and claims from those that are not as per the registered device indications and claims. In addition, the Authority recommends that the labeling include a general statement about these unapproved changes.

g) Have appropriate conditions for the monitoring and reporting of incidents associated with the emergency use of the device.

h) Have appropriate conditions concerning recordkeeping and reporting, including records for access by the Authority, with respect to emergency use of the device.

Annex A
(normative)

Pihak Berkuasa Peranti Perubatan
Medical Device Authority
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: sa.cm@mda.gov.my

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS

(In accordance with Medical Device (Exemption) Order 2016)

All fields are mandatory unless stated otherwise.

SECTION A : APPLICANT / COMPANY DETAILS
(This section is for the individual, institution or organization who or which takes responsibilities for the importation and/or placement the special access medical devices in Malaysia)

1. *Please tick the appropriate box:*

- ☐ Local manufacturer
- ☐ Registered medical practitioner *(obtains directly from the manufacturer for uses the special access medical device on his/her patient)*
- ☐ *An Authorized Person from a Local Organization / Company (Note: Shall have a permanent address in Malaysia)*
- ☐ *Others (Please Specify):*

2. Name of Applicant:

3. NRIC No./Passport:	4. Designation:

5. Name & Address of Organization:

6. Telephone No.:	7. Email Address:

8. Does the company already hold Establishment License?	☐ Yes If Yes, please state the company Establishment License Number: …… Company's Role : ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS

(In accordance with Medical Device (Exemption) Order 2016)

SECTION B : MEDICAL PRACTITIONER DETAILS (if applicable)
(*This section is for the medical practitioner who or which takes responsibilities for the importation and/or placement the special access medical devices in Malaysia)*

1. Name:	
2. Title:	3. Annual Practicing Certificate Number:
4. Telephone No.:	5. Email Address:
6. Health Care Facility Name & Address:	

SECTION C: MEDICAL DEVICE DETAILS

7. Please provide details of the medical device in **Appendix 1**.

SECTION D : CLINICAL JUDGEMENT/ PUBLIC HEALTH EMERGENCY OUTBREAK

1. Please prescribe the treatment for an individual patient specific:

(Notes: This should include an outline of the seriousness of the patient's condition and details of the past treatment. If other approved medical devices are available, the applicant will need to justify the use of special access medical device to those treatments. It is important for the justification to balance the availability of approved medical device against the seriousness of the patient's condition and to include an appraisal of the expected benefits from the use of unapproved medical device).

2. In case of the a request for Batch Release, please describe the emergency requiring treatment, and provide the number of the devices for one month:

SECTION E : MEDICAL DEVICE SAFETY INFORMATION

1. List the registered devices considered and provide a rationale as to why these registered devices would not adequately meet the requirements of the patient.

Device Name	Medical Device Registration Number	Rationale as to why this registered device would not adequately meet the requirements of the patient

Note. Please attach additional page if space is insufficient.

2. Summarize the known safety and effectiveness information in respect of the device.

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS

(In accordance with Medical Device (Exemption) Order 2016)

SECTION F : MEDICAL PRACTITIONER UNDERTAKING

(Medical Practitioners are required to make an undertaking that they will inform the patient for whom the device is intended of the risks and benefits associated with its use).

I, < Name of Medical Practitioner >, ID <IC No. >,

i. undertake to inform the patient, < Patient's ID >, who is to be treated with the device of the risks and benefits associated with the use of this special access medical device.
ii. confirm that I have informed the patient, < Patient's ID >, who is to be diagnosed or treated with the device of the risks and benefits associated with the use of this special access medical device.
iii. declare that the special access medical device to be used on the patient is to save the life of a patient, to help a patient suffering from a serious disease or condition when existing registered medical device have failed, unavailable or are unsuitable to provide a diagnosis, treatment or prevention for patients under my care.
iv. have obtained the informed consent of the patient, or the patient's legal representative, to the proposed diagnose/treatment.
v. will take full responsibility for the use of this special access medical device on the named patient listed above and shall adhere to the conditions of approval.
vi. will ensure that this medical device will be used or administered in accordance with its intended purpose and indications for use as stated in the product owner's instructions for use.

In the case of a batch release request (if applicable):

a) it is the sponsor's responsibility to maintain a distribution record with respect to the device.
b) Health care professionals are requested to return any unused devices to the sponsor.

I, < Name of Medical Practitioner >, ID <IC No. >,

i. Undertake to inform the patient(s) who are to be treated with the device of the risks and benefits associated with the use of this special access medical device.
ii. Confirm that if I cannot inform the patients, who are to be diagnosed or treated with the device of the risks and benefits associated with the use of this special access medical device, I attest that institutional policies will be followed.

Signature:

Date :

Health Care Facility Stamp :

NOTIFICATION OF MEDICAL DEVICES FOR SPECIAL ACCESS

(In accordance with Medical Device (Exemption) Order 2016)

SECTION G : ATTESTATION & DECLARATION

I, the undersigned hereby declare that :

i. This/these product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).

ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.

iii. The medical device(s) has/have met all the labeling requirements.

iv. The technical documentation of the special access device(s) is/are prepared in accordance with the format as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.

v. will take necessary action to register the medical device and acquire establishment license as stipulated under the Act 737 once Malaysia is free from the emergency situation.

Remark: Any kind of deletion in Section F please provide justification.

I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident that occur;

I hereby attest that the information and attachment provided on this notification is/are accurate, correct, complete and current to this date.

Signature:

Person Responsible Name:

Designation :

Date :

Company stamp :

Appendix 1

MEDICAL DEVICE DETAILS

Name of Medical Device:			
Grouping :	☐ Single ☐ System ☐ Family	Set ☐	
Brief Description:			
Brand:			
Identifier (catalogue or model number):			
Intended use of the device:			
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email :		
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Quantity to be Imported:			
Marketing Approval Status in other country(-ies) (Please : i. state the name (s) of country (ies) ii. provide evidence such as Declaration of Conformity/Device Licence/Registration Certificate/510k/etc)	☐ Registered /Licensed	☐ Exempted/ Notified	Others (please specify) ☐ ....
Configuration list (for grouped medical device) :	***Not Applicable for single medical device.***		

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description	Quantity to be Imported

Annex B
(normative)

Pihak Berkuasa Peranti Perubatan
Medical Device Authority
Kementerian Kesihatan Malaysia
Ministry of Health Malaysia
Portal: www.mda.gov.my
Email: sa.cm@mda.gov.my

NOTIFICATION OF USE OF ANAESTHESIA UNITS AS EMERGENCY VENTILATORS

All fields are mandatory unless stated otherwise.

SECTION A : APPLICANT / COMPANY DETAILS
(This section is for the individual, institution or organization who or which takes responsibilities for the importation and/or placement these medical devices into the market).

1. *Please tick the appropriate box:*

☐ Local manufacturer

☐ *An Authorized Person from a Local Organization / Company (Shall have a permanent address in Malaysia)*

☐ *Others (Please Specify):*

2. Name of Applicant:

3. NRIC No./Passport:	4. Designation:

5. Name & Address of Organization:

6. Telephone No.:	7. Email Address:

8. Does the company already hold an Establishment License?	☐ Yes If Yes, please state the company Establishment License Number: ..... Company's Role : ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer	☐ No

SECTION B : HEALTHCARE INSTITUTION INFORMATION (*This section is for the information of the anaesthesia machine installed at healthcare facilities)*	
9. Health Care Facility Name & Address:	
10. Telephone number & E-mail address	11. Person in charge
SECTION C: MEDICAL DEVICE DETAILS	
Please provide details of the medical device in **Appendix 2.**	
SECTION D : MEDICAL DEVICE SAFETY INFORMATION	
12. Summarize the known safety and effectiveness information in respect of the device.	
SECTION E : TECHNICAL SPECIALIST/CLINICAL APPLICATION SPECIALIST INFORMATION	
13. Name	
14. NRIC No./Passport:	15. Designation:
16. Name & Address of Organization:	
17. Telephone number:	18. E-mail address:
SECTION F : ATTESTATION & DECLARATION	
I, the undersigned hereby declare that : i. This/These product(s) is/are according to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737). ii. The device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012. iii. will provide training to the user including the explanation of potential risk to the user and patients. iv. will provide 24 hours technical support to the user during the emergency situation or when needed.	

v. The accessories and spare part are available and ready to supply to the healthcare facilities when needed.

vi. The medical device(s) has/have met all the labeling requirements set out in 6.1 of MDA/GD/0056.

vii. The technical documentation on the modification of the anaesthetic unit and is available upon request by the Authority.

Remark: Any kind of deletion in Section F please provide justification.

I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any adverse incident that occur during the operation of these devices.

I hereby attest that the information and attachment provided on this notification are accurate, correct, complete and current to this date.

Signature:

Name of Person Responsible:

Designation :

Date :

Company stamp :

Appendix 2

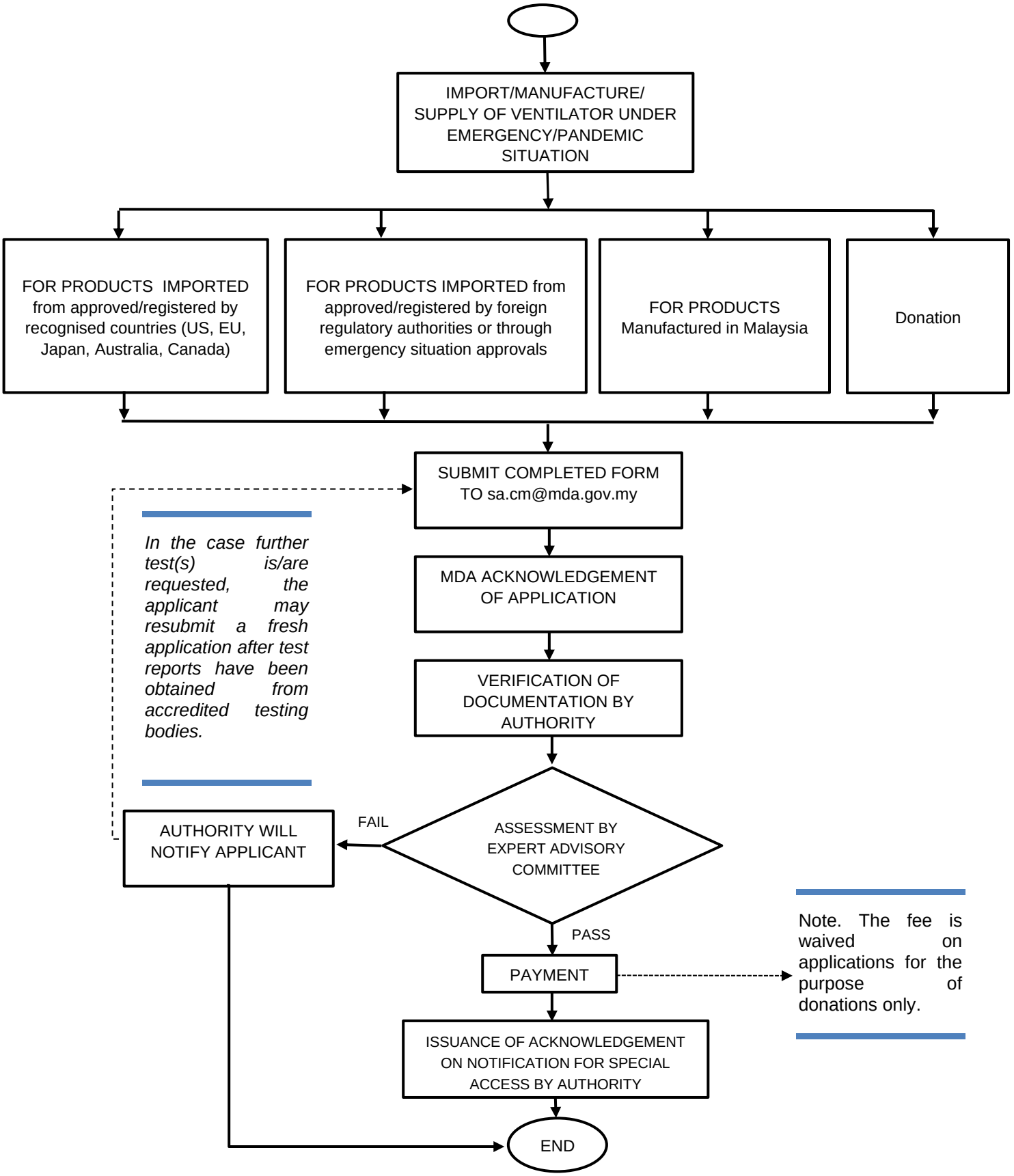
MEDICAL DEVICE DETAILS

Name of Medical Device:			
Grouping :	☐ Single ☐ Set ☐ System ☐ Family		
Brief Description:			
Brand:			
Serial number/lot/batch number/ manufacturing date (where applicable)			
Identifier (catalogue or model number):			
Intended use of the device:			
Manufacturer's Information:	Manufacturer's Name: *(as it appears on the label)* Contact Name and Title: Address (Number , Street, City, Country) Postal Code: Telephone : Email :		
Risk-Based Classification :		**Classification Rule:** (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Quantity to be supplied:			
Configuration list (for grouped medical device) :	***Not Applicable to single medical device.***		

No.	Name of device, accessories, constituent components, or articles as per product label:	Model	Brief Description	Quantity to be Imported

Annex C
(informative)

Special Acces flow chart for ventilator



Annex D
(informative)

List of available standards for ventilators

This annex provides a non-ehaustive list of recognised standards available related to ventilators, for reference and could be used to demonstrate compliance with essential principles for safety and performance requirements.

1. ISO 10651-3:1997 Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators
2. ISO 10651-4:2002 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators
3. ISO 10651-5:2006 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators
4. ISO 80601-2-12:2020, Medical electrical equipment - Part 2-12: Particular requirements for the basic safety and essential performance of critical care ventilators
5. ISO 80601-2-13:2011, Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
6. ISO 80601-2-55:2018, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
7. ISO 80601-2-72:2015, Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
8. ISO 80601-2-74:2017, Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
9. ISO 80601-2-79:2018, Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
10. ISO 80601-2-80:2018, Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
11. ISO 80601-2-84:2018: Medical electrical equipment. Part 2 to 84. Particular requirements for basic safety and essential performance of emergency and transport ventilators - especially the parts on ‘patient gas pathway’ safety
12. ISO 19223:2019: Lung ventilators and related equipment. Vocabulary and semantics
13. ISO 18562-1:2017 “Biocompatibility evaluation of breathing gas pathways in healthcare applications
14. ISO TR 21954:2018, Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator
15. IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
16. IEC 60601-1-8:2006: 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
17. EN 794-3:1998 +A2:2009: Particular requirements for emergency and transport ventilators

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[1] Health Sciences Authority, Singapore: *HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 Patients*, 2020

[2] MHRA: *Rapidly Manufactured Ventilator System (RMVS) v3.1*, March 2020

[3] Therapeutic Good Admistration , Australia: *COVID-19 information for clinicians on ventilators and alternative strategies when in short supply*, March 2020

[4] USFDA Draft Guidance, *Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency***,** March 2020**.**

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:portal.mda.gov.my