Medical Device Administrative Control System (MDACS)

Guidance Notes for Listing Class II/III/IV General Medical Devices

Guidance Notes: GN-02

中華人民共和國
香港特別行政區政府衞生署
Department of Health
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Revision history

Edition Number	Date of Revision	Summary of Revisions	Reference Number
0	2004	• First issue of GN-02 (Guidance Notes for Listing Class IV Medical Devices)	GN-02:2004(E)
1	7 July 2011	• Issue of revised GN-02 (Jul 2011 Edition) (Guidance Notes for Listing Class II/III/IV Medical Devices) • The revised GN-02 supersedes the existing GN-02 (Guidance Notes for Listing Class IV Medical Devices) and GN-05 (Guidance Notes for Listing Class II/III Medical Devices). • Application Form for Listing of Class II/III/IV Medical Devices is revised to MD-C2&3&4 (Jul 2011 Edition) • Reference is made to GN-00 for definitions and to TR-003 for classification of medical devices • Appendix 3 Sample Essential Principles Declaration of Conformity is added	GN-02:2011(E)
2	19 April 2021	• Update document format; • Rename of Medical Device Control Office to Medical Device Division; • Clause 5.3(Submission of applications) has been updated; • Clause 6 (Guide to Application Form MD-C2&3&4) has been updated; • Appendix 1 Sample Application Form for Listing of Class II/III/IV Medical Devices has been updated to MD-C2&3&4 (2021 Edition); and • Appendix 2 Sample Essential Principles Conformity Checklist has been updated to MD-CCL (2021 Edition)	GN-02:2021(E)
2.1	30 August 2021	• Appendix 1 Sample Application Form for Listing of Class II/III/IV Medical Devices has been updated to MD-C2&3&4 (2021 2nd Edition) • Modified the scope of accepted Marketing Approvals	GN-02:2021(E)
3	1 January 2022	• Appendix 1 Sample Application Form for Listing of Class II/III/IV Medical Devices has been updated to MD-C2&3&4 (2022 Edition);	GN-02:2022(E)

Edition Number	Date of Revision	Summary of Revisions	Reference Number
		• Note A003 and D001 in Clause 6 (Guide to Application Form MD-C2&3&4) has been updated; • Updated document format.	
4	1 January 2024	• Appendix 1 Sample Application Form has been removed • Appendix 2 Sample Essential Principles Conformity Checklist has been removed • Appendix 3 has been renamed to Appendix I • Modified the scope of accepted Marketing Approvals	GN-02:2024(E)
5	2 April 2024	• “Make” is replaced with “Manufacturer” • Modified the scope of accepted Marketing Approvals • Clause 5.5 (Time for vetting and approving an application) is added • Application Form “MD-C2&3&4” is renamed as “MD101” • Typo in Appendix I is corrected • Updated document format	GN-02:2024-1(E)
6	14 June 2024	• Clause 5.1, 5.2, 5.3 and 6.1 are revised • Clause 5.4 and 5.5 are deleted • Updated document format	GN-02:2024-2(E)
7	8 August 2024	• Addition of clause 5.4 (Notification of approval or rejection of application) • Clause 6 is revised (Appeal) • Updated document format	GN-02:2024-3(E)
8	13 October 2025	• Clause 7.1 is revised (Translation)	GN-02:2025(E)

Table of Contents

1. Introduction

1.1 This document is to provide guidance to applicants applying for inclusion of Class II/III/IV general medical devices into the List of Medical Devices under the Medical Device Administrative Control System (MDACS). It provides detailed information to the applicants for preparing the application submission. It supersedes the existing "Guidance Notes for Listing Class IV Medical Devices" (Guidance Notes GN-02) and "Guidance Notes for Listing Class II/III Medical Devices" (Guidance Notes GN-05) as it incorporates and updates the contents of these two guidance documents. Applicants should read this document in conjunction with the "Overview of Medical Device Administrative Control System" (Guidance Notes GN-01), "Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System" (Guidance Notes GN-00) and "Classification Rules for Medical Devices" (Technical Reference TR-003) to have a thorough understanding of the MDACS before making the submission. Applicants applying for listing medical devices other than Class II/III/IV general medical devices shall make reference to the corresponding Guidance Notes accordingly.

2. Definitions and abbreviations

2.1 Please refer to "Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System" (Guidance Notes GN-00) for the definitions and abbreviations of the terms that appear in this document.

3. The Way to Determine if a Medical Device is a Class II/III/IV General Medical Device

3.1 Classification of general medical devices

3.1.1 Based on the classification rules of the MDACS (which are in line with those promulgated by the International Medical Device Regulators Forum (IMDRF) (previously Global Harmonization Task Force (GHTF))), general medical devices are classified into four categories (Classes I to IV) according to their risk levels, Class IV being the category of the highest risk and Class I the lowest. The classification rules for defining the class of a general medical device are given in "Classification of General Medical Devices" (Technical Reference TR- 003).

3.2 Determining Class II/III/IV general medical devices by the classification rules

3.2.1 The applicant must take into consideration all the classification rules given in "Classification of General Medical Devices" (Technical Reference TR-003) in order to establish the proper classification for the device. If more than one rule is applicable to the device, the rules resulting in the highest classification of the device shall apply. The examples given in Table 1, Table 2 and Table 3 illustrate the application of the rules to determine whether a general medical device is of Class II, Class III and Class IV respectively.

Table 1 – Examples of Class II general medical devices

Devices	Class	Rule
Non-medicated impregnated gauze dressing	II	Rule 1
Anaesthesia breathing circuit	II	Rule 2
Device to warm or cool blood	II	Rule 3

Orthodontic wire	II	Rule 5
Single-use scalpel	II	Rule 6
Infusion cannula	II	Rule 7
Dental filling material	II	Rule 8
Muscle stimulator	II	Rule 9
Electronic thermometer	II	Rule 10
Feeding pump	II	Rule 11
Washer disinfector	II	Rule 15

Table 2 – Examples of Class III general medical devices

Devices	Class	Rule
Dressing for chronic ulcerated wounds	III	Rule 1
Hemodialyzer	III	Rule 3
Urethral stent	III	Rule 5
Insulin pen for self-administration	III	Rule 6
Brachytherapy device	III	Rule 7
Maxilla-facial implant	III	Rule 8
Lung ventilator	III	Rule 9
Apnoea monitor	III	Rule 10
Dialysis equipment	III	Rule 11
Contact lens solution	III	Rule 15
Condom	III	Rule 16

Table 3 – Examples of Class IV general medical devices

Devices	Class	Rule
Angioplasty balloon catheter	IV	Rule 6
Neurological catheter	IV	Rule 7
Cardiovascular catheter	IV	Rule 7
Vascular stent	IV	Rule 8
Implantable pacemaker	IV	Rule 8
Breast implant	IV	Rule 8
Heparin-coated catheter	IV	Rule 13
Catgut suture	IV	Rule 14
Intrauterine contraceptive device	IV	Rule 16

3.2.2 The examples shown in Table 4 are either not medical devices or not Class II/III/IV general medical devices according to the classification rules.

Table 4 – Examples of non-Class II/III/IV general medical devices

Devices	Class	Rule
Simple wound dressing	I	Rule 1
Administration set for gravity infusion	I	Rule 2

Urine collection bottle	I	Rule 4
Dental impression material	I	Rule 5
Manually operated surgical drill	I	Rule 6
Examination lamp	I	Rule 12
Syringe preloaded with vaccine/drug	N.A. (Medicinal Product)	Rule 13 not applicable (the action of the medicinal product not ancillary to that of the device)

4. Persons Eligible to Apply for the Inclusion of a Class II/III/IV General Medical Device into The List of Medical Devices

4.1 Only the Local Responsible Person (LRP) in relation to the device can make the application. Please see Clauses 3, 4 and 5 of the Guidance Notes GN-01 for the requirements and obligations of an LRP.

5. Application Procedures

5.1 Submission of applications

5.1.1 An application for inclusion of a Class II/III/IV general medical device into The List of Medical Devices must be made on the Form MD101 through the online Medical Device Information System (MDIS) (https://mdis.mdd.gov.hk/).

5.2 Acknowledgement of application

5.2.1 On receiving an application, the MDIS will acknowledge the receipt via notification to the applicant's registered email. If an applicant does not receive the acknowledgement within two (2) weeks after sending in an application, he may contact the MDD to check if the submission has been received by the MDD.

5.3 Time for vetting and approving an application

5.3.1 The vetting and approval of an application for listing a device should normally be completed within 12 weeks following the submission of the application and all the required supporting information, including labelling samples.

5.4 Notification of approval or rejection of application

5.4.1 An application for inclusion of a device into The List of Medical Devices may either be rejected, approved, or approved conditionally. If the application is approved or conditionally approved, a listing number will be assigned to the device. The LRP will be notified of the rejection, approval, or conditional approval, along with any listing number assigned to the device (in the case of approval or conditional approval). Where the application is approved conditionally, MDD will also specify the special conditions (e.g. one requiring the manufacturer to conduct certain post-market surveillance studies) on which the approval is given. Failure of the manufacturer or the LRP to comply with those conditions can result in their names and the device being removed from The Lists.

6. Appeal

6.1 The LRP may appeal against a decision of the Medical Device Listing Approval Board to reject an application, or the conditions imposed to a conditionally approved application, or to remove a Listed medical device from the List of Medical Devices within fourteen (14) working days of being notified of the decision.

6.2 To appeal, the LRP shall write to the Secretary to Medical Device Administration Appeal Committee, c/o Medical Device Division, stating its grounds of appeal.

6.3 The lodging of an appeal against a decision of MDD does not suspend the decision unless MDD decides otherwise.

6.4 An appeal lodged after the time limit specified in clause 6.1 will not be considered.

6.5 The LRP will be notified of the outcome of the appeal application within four (4) weeks following the submission of the appeal application and all the required supporting information (if applicable). The decision of the Medical Device Administration Appeal Committee shall be final.

7. Guide to Application Form MD101

7.1 The following table explains how to fill in the application form MD101 for Class II/III/IV general medical devices.

Table 5 – Guidance for completing the application form MD101

Item	Explanation
A001	• Particulars of the manufacturer including the name (in English and/or Chinese), address of head office (in English and/or Chinese), post code, country, contact person, telephone number, fax number, email address and the website shall be provided. The name and address of the manufacturer shall be the same as those stipulated in the marketing approval certificate(s) or MDACS Conformity Assessment Certificate recognized by MDD and the ISO 13485 latest edition (or equivalent) certificate provided by the applicant. These information are considered essential for the application.
A002	• If the manufacturer has a registered place of business in Hong Kong, both boxes shall be checked with a copy of the business registration enclosed under index (A1) of the submission folder. The contact person, telephone number, fax number and email address of the Hong Kong office shall be provided.
A003	• The manufacturer shall implement a quality management system and the appropriate box shall be checked to indicate whether it is a full quality management system or a partial system. If it is a partial system, the processes covered shall be specified. The boxes corresponding to the standard shall be checked and the certification body of the quality management system shall be specified. A copy of the ISO 13485 latest edition (or equivalent) certificate shall be enclosed under index (A2) of the submission folder. This information is considered essential for the application.

Item	Explanation
A004	• The Local Responsible Person (LRP) must either be a legal person incorporated in Hong Kong or a natural or legal person with a registered place of business in Hong Kong e.g. a company, a solicitor firm. • If the manufacturer has a registered place of business in Hong Kong, it could decide either to act as the LRP itself or to designate another body to be the LRP. If the manufacturer has no registered place of business in Hong Kong, it must designate another body meeting the requirements of an LRP to make the application.
B001	• The details of the LRP including the name (in English and/or Chinese), address (in English and/or Chinese), contact person, position of contact person, telephone numbers, fax number and email address shall be provided. The details must include, among other things, a telephone number that the public may call for enquiries, as well as a mobile telephone number through which the LRP may be contacted by the MDD after office hours. The name and address of the LRP shall be the same as those stipulated in the Hong Kong business registration. This information is considered essential for the application. • A copy of the Hong Kong business registration shall be enclosed under index (B1) of the submission folder.
B002	• The date of designation as the LRP of the device shall be quoted and a copy of the designation letter issued by the manufacturer shall be enclosed under index (B2) of the submission folder. This information is considered essential for the application.
B003	• If the LRP has implemented any quality management system, the system and, if applicable, the certification body shall be specified. A copy of the certificate of the quality management system shall be enclosed under index (B3) of the submission folder if applicable.
B004	• A copy of the documented procedures for Keeping of supply records, Complaint handling, Management of product recalls and field safety notices, Handling of reportable adverse events in Hong Kong, Tracking of specific medical devices (if applicable), Maintenance and service arrangements (if applicable), shall be enclosed under index (B4) of the submission folder. This information is considered essential for the application. • In case the applicant already has medical device listed under the MDACS, the LRP number shall be quoted without re-submitting the procedures if the procedures indicated under items (i) to (vi) have been submitted and there is no change to the procedures.
B005	• If the LRP is also an importer and/or distributor of the device, the box shall be checked. The Listing No. of the importer and/or distributor shall be quoted (if applicable).
B006	• If, to the knowledge of the LRP, the device has already been listed (albeit with another LRP), the box shall be checked with the known existing Listing Number of the device given.
C001	• The Manufacturer, brand name and model of the medical device, medical device family, medical device series or medical device system shall be specified in English and/or Chinese and they will be used as the identifier of the device. This information is considered essential for the application. • For the purpose of this listing, brand name may cover trade name, family name, series name or system name and model may cover other identification details such as model number or product number.

Item	Explanation
C002	• The appropriate box(es) shall be checked to indicate whether it is an application for a single medical device, a medical device family, a medical device series or a medical device system. • **A medical device family** is a group of medical devices having the same manufacturer, device description and classification, intended use, design, construction and performance e.g. catheters of different diameters and lengths. For each member of the medical device family, please provide its identifier(s) (e.g. product number), a brief account of its characteristics that distinguish it from other members (e.g. dimensions of its various parts). • **A medical device series** is a group of medical devices belonging to the same model series of a manufacturer and having the same device classification, intended use, but differing only in minor features or functions that do not present significantly different safety, performance and effectiveness issues. In principle, the designs, labelling, manufacturing processes and performance specifications cannot be significantly different between members of a series. For each member of a medical device series, please provide its identifier(s) (e.g. model number), and a brief account of its minor features that distinguish it from other members. • **A medical device system** is a medical device comprising a number of medical devices (component medical devices) intended to be used together to fulfil the system's intended use. All component medical devices shall be placed on the market under the name of the same manufacturer. A short description on how the component medical devices are used together to achieve the intended purpose of the medical device system shall be provided. For each component medical device of a medical device system, please provide its Asian Medical Device Nomenclature System (AMDNS) term (if an AMDNS term is not available for a particular component, a short description shall be provided) and the corresponding AMDNS code, its identifier(s) (e.g. model number), and a brief description of its intended use. • Additional information concerning the medical device family, medical device series or medical device system could be provided on separate sheets in formats similar to MDS-01 and MDS-02 (see C006) and enclosed under index (C1) of the submission folder.
C003	• The Asian Medical Device Nomenclature System (AMDNS) term of the device together with the corresponding AMDNS code shall be specified. If there is no applicable AMDNS term, a short description of the device shall be entered. The AMDNS is available at the MDD website for reference by applicants.
C004	• If there is any commonly used description of the device, it shall be provided.
C005	• The intended use of the device shall be specified in English and/or Chinese and it shall be in agreement with the information provided in the labelling and the marketing approvals obtained from the GHTF founding members or a MDACS Conformity Assessment Certificate obtained from a conformity assessment body recognized by the MDD.
C006	• All accessories for the device shall be specified. An accessory is regarded as an article intended specifically by its manufacturer to be used with the device to enable that device to be used in accordance with its intended purpose. • For a medical device series or medical device system, please indicate the member/component medical device with which each accessory is intended to work together to achieve the intended use. • Where applicable, the details of all the accessories of a medical device including their identifier(s) (e.g. part number) and descriptions should be provided on separate sheets in a format similar to MDS-02 and enclosed under index (C1) of the submission folder.
C007	• Please check the appropriate box(es) to indicate the relevant characteristics of the device.

Item	Explanation
C008	• The class of the medical device shall be specified. The reasons in details (including the classification rule number and the corresponding description of the rule with which the medical device compiles) for classifying the device as a Class II/III/IV general medical device shall also be provided. The applicant shall refer to "Classification of General Medical Devices" (Technical Reference TR-003) for the classification rules.
C009	• All the manufacturing sites for the medical device(s) within the scope under this application shall be specified. For a medical device system, all manufacturing sites for the medical device system as well as component medical devices shall be provided. Those manufacturing sites of the same manufacturer but not used for the production of the device to be marketed in Hong Kong need not be quoted. Besides, manufacturing sites or sub-contractors not engaged for production of the whole medical device but just a part of or some constituting components of the medical device need not be included. • Copies of ISO 13485 certificates covering the manufacturing sites shall be provided. The name and address of the manufacturing sites shall be the same as those stipulated in the ISO 13485 certificates. Where applicable, information on the manufacturing sites should be provided on separate sheets enclosed under index (C1) of the submission folder.
C010	• A summary of all recalls, suspensions, reportable adverse events, banning of the device in other countries or post-market surveillance studies, shall be provided under index (C2) of the submission folder. • Where there are any recalls in progress, details and current status of the recalls shall be provided. • Where there are any adverse events involving the same device or a design close to the device reported to overseas regulatory authorities, the following information shall be provided: (i) Dates of the events; (ii) To which regulatory agencies, and when, the events were reported; (iii) Causes of the events; (iv) Number of deaths and the serious injuries in these events; and (v) Corrective and preventive actions taken (including those taken to prevent recurrence of similar events). • Where there is any banning of the device, the dates, causes and related regulatory agents shall be provided. • Where there are any proactive post-market surveillance studies conducted, details and results of those studies shall be provided.
C011	• Specific characteristics of the device shall be indicated by checking the appropriate box(es), including whether the device is for single use, supplied as sterile product, requires special precautions for disposal, intended to be used/operated by healthcare professionals only or by laypersons, and whether it is for self-use. These information shall be identical to the specifications in the labelling.
C012	• If the device requires regular servicing, testing, checking or calibration, the appropriate box shall be checked. • Where repairs and servicing are provided by the applicant or other parties appointed, please specify whether all or only some of the services are performed in Hong Kong. • If technical support from the manufacturer is provided, the appropriate box shall be checked. • This information is considered essential for the application.

Item	Explanation
C013	• If the instructions for use are available in either English, Chinese, or both languages, the appropriate boxes shall be checked. Devices intended for self-use by consumers must be accompanied by instructions for use written in both English and Chinese. • All labelling including instructions, manuals, device and package labels (as specified in the Technical Reference TR-005) and Special Listing Information (as specified in the Guidance Notes GN-01) shall be submitted under index (C3) of the submission folder. Where the labelling is provided on the packaging and there is no separate instruction manual, the packaging or clear scanned digital colour images or digital colour photographs in PDF or JPEG format showing all the labelling information is acceptable as an alternative. However, the LRP may be required to provide a sample of the device for inspection or testing if considered necessary and practicable. • If electronic labelling is included, the corresponding internet linkage shall be provided. • Where the labelling submitted does not include clear images of the device and/or its associated accessories, clear scanned digital colour images or digital colour photographs in PDF or JPEG format showing the front, side and back views of the device and/or its associated accessories should be provided. Device brochures, demonstration video clips and/or animation clips illustrating the usage and applications of the device should be provided as far as possible. • The locations in the submitted samples where the Indications for use; Contraindications against use; Cleansing, disinfection and/or sterilization procedures; User precautions; and Disposal precautions can be found shall be given in the appropriate space.
C014	• Please check the appropriate boxes. If the device is subject to the provisions under the Radiation Ordinance (Cap. 303), the Pharmacy and Poisons Ordinance (Cap. 138), the Antibiotics Ordinance (Cap. 137) or the Dangerous Drugs Ordinance (Cap. 134), a copy of the required licence (e.g. Irradiating Apparatus Licence, Wholesale Poisons Licence) shall be enclosed under index (C4) of the submission folder. (Note: The ordinances listed under this item do not mean to be exhaustive. It is the applicant's responsibility to ensure compliance with other relevant ordinances.)
C015	• If a MDACS Conformity Assessment Certificate issued by one of the Conformity Assessment Bodies recognized by MDD is available, the appropriate box shall be checked and the Conformity Assessment Body number shall be quoted. A copy of Conformity Assessment Certificate shall be submitted under index (C5) of the submission folder. (Note: If applicants have already acquired the MDACS Conformity Assessment Certificates for their products, they may submit the Conformity Assessment Certificates in lieu of the Essential Principles Conformity Checklists (MD-CCL); Risk Analysis Reports/Summaries; and Clinical Evaluation Documents for the corresponding products. However, the applicants may be required to submit these documents later if deemed necessary. It is the applicants' obligation to prepare these documents and make them available for checking and verification under the MDACS. The unavailability of these documents may render their applications unsuccessful.)
C016	• If the device complies with any international or national safety standards, the standards shall be specified in the space provided. • There shall be a risk analysis conducted and the report or the summary shall be provided under index (C6) of the submission folder. This information is considered essential for the application. • Where there are any type tests performed by the manufacturer or any other party, the test reports and certificates shall be provided under index (C4) of the submission folder. • For devices containing biological materials or medicinal substances and/or materials that will come into contact with body tissues and/or fluids, further information (e.g. biological safety data, biocompatibility report, and certificates of analysis of the materials/substances, etc.) shall be provided upon request. • For devices emitting ionizing radiation, further information (e.g. radiation source and materials for shielding of radiation) shall be provided upon request.

Item	Explanation
C017	• Clinical evaluation is the review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation (please refer to Guidance Notes GN-00 for the definition of clinical investigation). It is a process to establish conformity of the device with the pertinent Essential Principles given in "Essential Principles of Safety and Performance of Medical Devices" (Technical Reference TR-004) and to demonstrate that the device performs as intended by the manufacturer. It establishes the acceptability of risks and side effects when weighed against the intended benefits of the device. The clinical evaluation and its outcome must be documented in a clinical evaluation report. • Please check the appropriate box(es) and enclose the relevant documents under index (C7) of the submission folder. The clinical evaluation report shall be provided upon request.
D001	• If there are approvals for the device to be marketed in any of the GHTF founding members namely Australia, Canada, the European Union (EU), Japan and the USA; Chinese Mainland, South Korea and/or Singapore, the appropriate boxes shall be checked and copy of the approval documents shall be provided under index (D1) of the submission folder. If the medical devices are approved for marketing in EU, a copy of the EC Declaration of Conformity shall also be submitted together with a copy of the EC certificate(s). To facilitate consideration of the application, applicants are advised to submit all relevant marketing approval certificates as far as possible. • Where any of these approvals have been obtained on or before 31 December 2004, the Essential Principles Conformity Checklist (Form MD-CCL) shall be submitted upon request. Otherwise, the duly completed Essential Principles Conformity Checklist (Form MD-CCL) shall also be provided under index (D1) of the submission folder. • Alternatively, if the applicants could provide the Essential Requirements / General Safety and Performance Requirements Checklist in accordance with relevant EU Medical Device directives or regulations and have sufficient evidence that their products also comply with the MDACS requirements, they may submit the Essential Requirements Checklist and an Essential Principles Declaration of Conformity in lieu of the MD-CCL. • Where no such marketing approval has been obtained, the application will not be processed unless a MDACS conformity assessment certificate issued by one of the Conformity Assessment Bodies (CAB) recognized by the MDD could be provided.

8. Enquiries

8.1 Enquiries concerning this document and the Medical Device Administrative Control System should be directed to:
Medical Device Division, Department of Health.
Telephone number: 3107 8484
Facsimile number: 3157 1286
Email address: mdd@dh.gov.hk
Website: www.mdd.gov.hk

9. References

9.1 Department of Health. Guidance Notes for Definitions and Abbreviations for Medical Device Administrative Control System. Guidance Notes GN-00.

9.2 Department of Health. Overview of the Medical Device Administrative Control System. Guidance Notes GN-01.

9.3 Department of Health. Classification of General Medical Devices. Technical Reference

TR-003.

9.4 Department of Health. Essential Principles of Safety and Performance of Medical Devices. Technical Reference TR-004.

9.5 Department of Health. Additional Medical Device Labelling Requirements. Technical Reference TR-005

10. Sample MDS-01 for reference

Additional information of medical device system

"ABC Medical / VGOOD PMS-123" Monitoring Systems, Physiologic *comprises a physiologic monitor (item 1), a remote control keyboard (item 2), a module rack (item 3) and various physiological and printing modules (item 4 to 9). The remote control keyboard and the module rack are connected directly to the physiologic monitor. Users can plug into the module rack any physiological modules (items 4 to 8) to enable the physiologic monitor to display, record and alarm respective physiological parameters depending on patient needs. A printing module (item 9) is available to provide print-out of physiological parameters.*

Details of the functions of the medical device system and respective component medical devices can be found in the Operator's Manual.

	AMDNS Term / Device Description	***AMDNS Code***	***Identifier***	***Functions/Purpose***
1.	*Monitors, Bedside, Physiologic, Modular*	*20171*	*PMS-VDU*	*For displaying, recording, alarming of physiological parameters, depending which modules are being plugged into the module rack (item 3)*
2.	*Keypads, Computer/Computerized System, Remote Control*	*22858*	*PMS-RCK*	*For users to enter data and commands to control the functions of the physiologic monitoring system*
3.	*Physiologic Monitor Module Housings*	*22856*	*PMS-SMR*	*For the connection of modules (housing of modules) to the patient monitor. The maximum number of modules that can be plugged into the rack is 8*
4.	*Physiologic Monitor Modules, Electrocardiography*	*20771*	*PMS-ECR*	*Plugged into the module rack (item 3), for measuring patient ECG and respiration rate (using impedance method) to identify episodes of arrhythmia and apnoea*
5.	*Physiologic Monitor Modules, Pulse Oximetry*	*20781*	*PMS-SPO*	*Plugged into the module rack (item 3), for measuring transcutaneously oxygen concentration (SpO_2) in arterial blood (using spectrophotometry method).*
6.	*Physiologic Monitor Modules, Noninvasive Blood Pressure*	*20773*	*PMS-NBP*	*Plugged into the module rack (item 3), for measuring blood pressure non-invasively (using oscillometric method)*
7.	*Physiologic Monitor Modules, Invasive Blood Pressure*	*20772*	*PMS-IBP*	*Plugged into the module rack (item 3), for measuring invasive blood pressure (direct method)*

	AMDNS Term / Device Description	***AMDNS Code***	***Identifier***	***Functions/Purpose***
8.	*Physiologic Monitor Modules, Temperature*	*20779*	*PMS-TMP*	*Plugged into the module rack (item 3), for measuring patient's body temperature*
9.	*Paper, Recording*	*15639*	*PMS-PRN*	*Plugged into the module rack (item 3), for providing print-out of patient related data from various physiological modules (items 4 – 8)*

11. Sample MDS-02 for reference

Accessories of "ABC Medical / VGOOD PMS-123" Monitoring Systems, Physiologic

	AMDNS Term / Device Description	***AMDNS Code***	***Identifiers***	***Medical Device/ Component Medical Device to be used with***
1.	*Cables/Leads, Electrocardiography*	*15754*	*PMS-ACC-ECR-01* *PMS-ACC-ECR-02* *PMS-ACC-ECR-03* *PMS-ACC-ECR-04* *PMS-ACC-ECR-05*	*"PMS-ECR" ECG/Resp. Module*
2.	*Probes, Pulse Oximeter*	*17594*	*PMS-ACC-SPO-01* *PMS-ACC-SPO-02* *PMS-ACC-SPO-03* *PMS-ACC-SPO-04*	*"PMS-SPO" SpO_2 Module*
3.	*Physiologic Monitor Modules, Noninvasive Blood Pressure*	*20773*	*PMS-ACC-NBP-01* *PMS-ACC-NBP-02* *PMS-ACC-NBP-03* *PMS-ACC-NBP-04* *PMS-ACC-NBP-05* *PMS-ACC-NBP-06*	*"PMS-NBP" NIBP Module*
4.	*Physiologic Monitor Modules, Invasive Blood Pressure*	*20772*	*PMS-ACC-IBP-07* *PMS-ACC-IBP-08* *PMS-ACC-IBP-09* *PMS-ACC-IBP-10* *PMS-ACC-IBP-11* *PMS-ACC-IBP-12* *PMS-ACC-IBP-13* *PMS-ACC-IBP-14*	*"PMS-IBP" IBP Module*
5.	*Probes, Thermometer*	*13125*	*PMS-ACC-TMP-01* *PMS-ACC-TMP-02* *PMS-ACC-TMP-03*	*"PMS-TMP" Temperature Module*
6.	*Paper, recording*	*15639*	*PMS-ACC-PRN-01*	*"PMS-PRN" Chart Recorder Module*

12. Appendix I

<Name of Manufacturer/Local Responsible Person>

<Address of Manufacturer/Local Responsible Person>

<Date>

Medical Device Division,
Department of Health.
Room 604, 6/F,
14 Taikoo Wan Road,
Taikoo Shing, Hong Kong

Dear Sirs

Product: <Manufacturer> <Brand Name and Model(s)>

<Product Description>

Manufactured by <Manufacturer>

<Address of Manufacturer>

We declare that the captioned product fully complies with all the relevant clauses stipulated under the Essential Principles of Safety and Performance of Medical Devices as required under the Medical Device Administrative Control System. We undertake to provide the necessary evidence to demonstrate the compliance within two weeks upon request.

Yours faithfully,

<Signature>

<Name and Title>

<Company Name>