LEADER CERTIFICATION SDN BHD

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICE

24240279

2024

9th September 2024

Initial Certification Assessment

AUDIT REPORT

NEXGEN MEDSOLUTIONS SDN. BHD.

L-2-11, Plaza Damas,
No. 60, Jalan Sri Hartamas 1, Sri Hartamas,
50480 Kuala Lumpur

Audit Team Leader: Daniel Manaf
Audit Team Member: NA

1. Definition

No.	Terminology	Explanation
1	Major Nonconformity (Major NC)	A major deviation from the GDPMD standard that jeopardizes the organization's capacity to achieve its goals or conform to regulatory requirements. When major nonconformities arise, it signifies a fundamental failure in the management system and often calls for immediate corrective action. An additional visit may be required to verify the action taken against it.
2	Minor Nonconformity (Minor NC)	A slight deviation from the GDPMD standard's requirements or violation of regulatory requirements. This indicates a situation where there is a minor deviation from certain processes or procedures, but it does not pose a significant risk to the overall effectiveness of the management system. Although minor nonconformities do not necessitate immediate action, they should still be acknowledged and corrected within a reasonable timeframe. Failure to address repeated minor nonconformities may lead to their progression into major nonconformities.

2. Scope of GDPMD Certification

DETAILS ON ESTABLISHMENT				
Establishment Name	:	Nexgen Medsolutions Sdn. Bhd.		
SSM Registration No.	:	202101028287 (1428587-U)		
Address	:	L-2-11, Plaza Damas, No 60 Jalan Sri Hartamas 1, Sri Hartamas, 50480 Kuala Lumpur		
Contact Information	:	Contact Person Name	Jessica Yeoh	
		Telephone Number	+6012 320 7504	
		Fax Number	NA	
		E-Mail Address	jessica@fomema.com.my	
Other Premises Covered by This Certification	:	Name Of Establishment	NA	
		Address Information	NA	
		Contact Information	NA	
Number of Employee	:	5		
Roles Of Activities	:	☐	Authorized Representative	
		☐	Importer	
		☒	Distributor	
		☐	Other:	
Outsourced Activities Information	:	Outsource Company	Outsourced Activities	GDPMD Certification
		NA	NA	
Special Storage and Handling Conditions	:	Medical Device	Condition	
			NA	

DETAILS OF CERTIFICATION		
Type of Assessment	☒	Initial Certification Assessment
	☐	Surveillance Assessment
	☐	Recertification Assessment
	☐	Others:
Regulatory requirement	Good Distribution Practice for Medical Device	
Audit Criteria	GDPMD Revision 1 – Version 2015	
Excluded Clauses (including justification)	i. Clause 21-22 Storage and Handling & Stock Rotation; the company does not intend to keep any stock of medical device ii. Clause 27 Specific Traceability Requirements for Implantable Medical Devices; the company does not dealing with implantable medical device iii. Clause 28 Specific Requirements for Active Medical Devices; the company does not involve in installation, testing, commissioning, maintenance and calibration activities iv. Clause 29 Outsource Activity; the company does not outsource any activity within scope of certification v. Clause 31-36 Secondary Assembly including Repackaging; the company not dealing with secondary assembly activities	
Authorized Representative Information	☒	The Establishment is an Authorized Representative
	☐	The Establishment is not an Authorized Representative
Scope Of Certification	☐	Import;
	☐	Storage And Handling;
	☐	Warehousing;
	☐	Secondary Assembly;
	☒	Distribution (Including Transportation);
	☐	Installation, Testing & Commissioning (Including the Required Facilities);
	☐	Maintenance And Calibration (Including the Required Facilities);
	☒	Documentation (Including Traceability of Medical Devices).
DETAILS ON CAB/ CAB AUDIT TEAM		
Audit Man-Hour	8 man-hours/ 1 man-day	
CAB Name	Leader Certification Sdn. Bhd.	
CAB Registration No.	MDA/CAB-025	
CAB Registration Validity Date	18/10/2023 – 17/10/2026	
Lead Auditor	Daniel Manaf	
CAB Auditor	RA-A22-06	

Registration No.	
Cab Auditor Proficiency Validity Date	29/06/2022 - 29/06/2025
Team Member	NA
Trainee/ Observer	NA

AUDIT ASSESSMENT PARTICIPANTS					
No.	Name	Position	Opening Meeting	Closing Meeting	Interviewed (Processes)
1	Jessica Yeoh	Business Development Manager	/	/	Management, Operation
2	NA				
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

3. Audit Preparation and Methodology

3.1 Audit objectives and criteria

Audit Objective(s):	☒	The management system conforms with all the requirements of the audit standards
	☐	The management system implementation is continuously in accordance to the requirements of the audit standards
	☐	The organization has established, implemented, maintained and continually improved its MS, including the processes needed and their interactions
	☐	Other:
Audit Criteria(s)	☒	Standard: GDPMD MDARR NO. 1
	☒	Act: Medical Device Act 2012
	☒	Regulation: Medical Device Regulations 2012, Medical Device Regulations 2019
	☐	Other:

3.2. Audit methodology

The audit team has conducted a process-based audit focusing on the significant aspects, risks and objectives. The auditor(s) have used audit procedures to collect evidence in sufficient quantity and quality to validate the conformity of the management system of the organization. The use of audit procedures in a systematic way reduces the audit risk and reinforces the objectivity of the audit conclusions.

The audit team has used a combination of evidence collection procedures to create their audit test plan. The audit methods used consisted of interviews, observations of activities, review of documentation and records, technical tests and analysis of sampling. The sampling method used during this audit was a systematic sampling (or interval sampling) technique with minimal margin error.

3.3. Audit planning and process

GDPMD					
1: Main Assessment **3**: Surveillance 2 **2:** Surveillance 1 **4**: Recertification		**Plan**			
		1 2024	**2 2025**	**3 2026**	**4 2027**
Contact Information		Jessica	Jessica	Jessica	Jessica
Part 1 Preliminary					
	Objective, scope and application	☒	☒	☒	☒
Part 2 Organization & GDPMD Regulatory Compliance System					
4	Organization	☒	☒	☒	☒
5	GDPMD Regulatory Compliance System - General	☒	☒	☒	☒
6	Documentation	☒	☒	☒	☒
7	Document control	☒	☒	☒	☒
Part 3 Establishment Responsibilities					
8	Responsibilities and authorities	☒	☒	☒	☒
9	Designated Person	☒	☒	☒	☒
10	Management review	☒	☒	☒	☒
11	Review input	☒	☒	☒	☒
12	Review output	☒	☒	☒	☒
Part 4 Resource Management					
13	Personnel	☒	☒	☒	☒
14	Training, competency and awareness	☒	☒	☒	☒
15	Infrastructure	☒	☒	☒	☒
16	Work environment	☒	☒	☒	☒
17	Cleanliness and pest control	☒	☒	☒	☒
Part 5 Supply Chain and Device Specific					
18	Authorization	☒	☒	☒	☒
19	Communication channels	☒	☒	☒	☒
20	Receipt of stock	☒	☒	☒	☒
21	Storage and stock handling	☐	☐	☐	☐
22	Stock rotation	☐	☐	☐	☐
23	Delivery to customers	☒	☒	☒	☒
24	Control of nonconforming including returned MD	☒	☒	☒	☒
25	Disposal of medical devices	☒	☒	☒	☒
26	Traceability	☒	☒	☒	☒
27	Specific traceability requirements for implantable MD	☐	☐	☐	☐
28	Specific requirements for active medical devices	☐	☐	☐	☐
29	Outsourced activities	☐	☐	☐	☐
30	Counterfeit adulterate, unwholesome and tampered MD	☒	☒	☒	☒
31-36	Secondary assembly including repackaging	☐	☐	☐	☐
Part 6 Surveillance and Vigilance					
37	Surveillance and Vigilance - General	☒	☒	☒	☒
38	Medical device complaints	☒	☒	☒	☒
39	Distribution records	☒	☒	☒	☒
40	Field corrective action (FCA) & field safety notice (FSN)	☒	☒	☒	☒
41	Recall	☒	☒	☒	☒
42	Mandatory problem reporting	☒	☒	☒	☒
43	Internal audit	☒	☒	☒	☒
44	Corrective action	☒	☒	☒	☒
45	Preventive action	☒	☒	☒	☒
Additional requirements					
NA	Use of logo and accreditation mark	☒	☒	☒	☒
NA	Other: NA	☐	☐	☐	☐
Remarks:	NA				
Actual Audit Date		**2024**	**2025**	**2026**	**2027**

3.4. Previous audit results

The results of the last audit of this system have been reviewed, in preparation for this audit in particular to assure appropriate correction and corrective action have been implemented to address any nonconformity identified. This review has concluded that:

☐ any nonconformity identified during previous audits has been corrected and the corrective action continues to be effective

☐ any nonconformity identified during previous audits has not been addressed adequately and the specific issue has been re-defined in the nonconformity section of this report

☒ N/A (no previous audit or no nonconformity during the previous audit)

No	Findings	Action	Status
	NA		

3.5 Opening and Closing Meeting

Opening Meeting Checklist		
No	**Detail**	**Tick**
1	introduction of the participants, including an outline of their roles	√
2	confirmation of the scope of certification	√
3	confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements i.e. date and time for the closing meeting, interim meetings, etc	√
4	confirmation of formal communication channels between the audit team and the client	√
5	confirmation that the resources and facilities needed by the audit team are available;	√
6	confirmation of matters relating to confidentiality;	√
7	confirmation of relevant work safety, emergency and security procedures for the audit team;	√
8	confirmation of the availability, roles and identities of any guides and observers;	√
9	the method of reporting, including any grading of audit findings;	√
10	information about the conditions under which the audit may be premature terminated;	√
11	confirmation that the audit team leader and audit team representing the certification body is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;	√
12	confirmation of the status of findings of the previous review or audit, if applicable;	√
13	methods and procedures to be used to conduct the audit based on sampling;	√
14	confirmation of the language to be used during the audit;	√
15	confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;	√
16	opportunity for the client to ask questions.	√

Closing Meeting Checklist		
No	**Detail**	**Tick**
1	informing the client that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty	√
2	the method and timeframe of reporting, including any grading of audit findings;	√
3	the certification body's process for handling nonconformities including any consequences relating to the status of the client's certification;	√
4	the timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit;	√
5	the certification body's post audit activities;	√
6	information about the complaint handling and appeal processes.	√
7	Any diverging opinion that are not resolved.	√
8	opportunity for the client to ask questions	√

4. Audit Notes

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**NA - Regulatory Requirement, Certification Mark**			
Status	**Audit Criteria**			
Comply	i	compliance towards requirement of Medical Device Act 2012 and its regulations		
Comply	ii	compliance towards any applicable regulatory/ standard requirement		
Comply	iii	NIL abuse usage of certification mark, logo, etc		
Evidence				
1. Nexgen Medsolutions Sdn Bhd, previously known as Goodcare Equipment Sdn Bhd, has been established in medical device industry since September 2021 whereas currently, located at Sri Hartamas 2. Verified SSM on the business address which tallied with the registered address for GDPMD Certification 3. Sighted business license for registered address by Dewan Bandaraya Kuala Lumpur 4. The registered address mainly cover for administration activities only 5. There is NIL offense towards Section 5 and Section 15 of Medical Device Act 2012				
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**4 Organization**				
Status	**Audit Criteria**				
Comply	i	Organization Structure	The establishment shall define the organization structure with the aid of organizational chart and indicate the responsibility, authority, and interrelationship of all key personnel.		
Comply	ii	Job Descriptions	The establishment shall define the duties and responsibilities with written job descriptions for every level of the organization.		
Comply	iii	Authority/ Resources for Managerial and Technical Personnel	The establishment shall ensure that managerial and technical personnel have the authority and resources needed to carry out their duties.		
Comply	iv	Regulatory Compliance System	The establishment shall set up and maintain a GDPMD regulatory compliance system and identify and correct deviations from the established system.		
Evidence					
a. NMS-F23 Organization Chart, rev. 0, eff. 01/08/2024 consist of Chairman, Director, Senior Manager (Finance & Administration), Senior Executive (Finance & Administration), Business Development Manager, Sales (Operation Executive) b. NMS-F22 Job Description (JD), eff. 01/08/2024 for each defined positions c. The company itself having total of 5 personnel d. GDPMD system has been established within organization since 1st August 2024					
Remark	NA				
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.			
	☐	Actions are needed to conform to requirements. See FINDINGS LIST			
	☐	The clause is excluded			

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**5 GDPMD Regulatory Compliance System**				
Status	**Audit Criteria**				
Comply	i.	GDPMD Compliance System Establishment	The establishment shall establish, document, and implement a GDPMD regulatory compliance system and maintain its compliance with the regulatory requirements.		
Comply	ii.	Process Identification	The establishment shall identify the processes needed for the GDPMD regulatory compliance system and their application for all categories of medical devices, regardless of the type or size of the organization.		
Comply	iii.	Process Sequence and Interaction	The establishment shall determine the sequence and interaction of these processes.		
Comply	iv.	Operation and Control Criteria	The establishment shall determine criteria and methods needed to ensure that both the operation and control of these processes are effective in ensuring compliance.		

Comply	v.	Resource and Information Availability	The establishment shall ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
Comply	vi.	Process Monitoring	The establishment shall monitor, measure, and analyze these processes.
Comply	vii.	Achieving Planned Results	The establishment shall implement actions necessary to achieve planned results and maintain the effectiveness of these processes to ensure compliance.
Comply	viii.	Regulatory Process Management	The establishment shall manage the processes in accordance with the regulatory requirements.
NA	ix.	Outsourced Process Control	The establishment shall identify and control outsourced processes in accordance with the regulatory requirements.
Evidence			
i. NMS-RCM Regulatory Compliance Manuak, rev. A, eff. 01/08/2024, which prepared by Designated Person and approved by Managing Director ii. RCM-QP-NMS Quality Policy, eff. 01/08/2024 approved by MD iii. Business Process Flow Chart which further outlined on the inter-relationship of company activities with GDPMD and regulatory requirement iv. NIL outsource activity at point of review v. The company currently fully rely with the principal whereas the goods will be delivered directly to customer upon order, in future			
Remark	#OBS 1: To revise exclusion of clause in Regulatory Compliance Manual on the outsourced activities as the declared activities on transportation to principal is not consider as outsource activity as per GDPMD standard		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**6 Documentation**				
Status	**Audit Criteria**				
Comply	i.	Regulatory Compliance Manual	The establishment shall establish and maintain a Regulatory Compliance Manual which includes information about the establishment's profile, activities, compliance to regulatory requirements, and obligations.		
Comply	ii.	GDPMD Compliance Scope	The manual shall include the scope of the GDPMD regulatory compliance system, including details of any exclusion or non-application.		
Comply	iii.	Medical Devices Compliance Status	The manual shall detail the medical devices the establishment deals with and their compliance status.		
Comply	iv.	Compliance Procedure & Document	The manual shall include procedures required by the GDPMD regulatory compliance system and reference to them, as well as documents needed for effective planning, operation, and control of processes.		
Comply	v.	Compliance Records	The manual shall include records required by the GDPMD regulatory compliance system.		
Comply	vi.	Activities, Personnel, and Conformity Assessment Information	The manual shall include information regarding the premises where activities are conducted, the personnel conducting them, and the medical device conformity assessment.		
Comply	vii.	Addressing Regulatory Requirements	The manual shall describe how the relevant and applicable regulatory requirements are addressed for each medical device in the scope of the GDPMD system.		
NA	viii.	Product and Process Documentation	For each medical device, the establishment shall establish a file containing documents that define product specifications, installation qualifications, distribution process, and, if applicable, installation and servicing.		
Evidence					
i. NMS-RCM Regulatory Compliance Manuak, rev. A, eff. 01/08/2024 ii. Scope - Distribution (including Transportation), and Documentation (including Traceability of Medical Devices) iii. Exclusion on Clause 21, 22, 27, 28, 29, 31 - 36 with valid justification. iv. Nil other site available v. Annex 1 List of Devices dealt with by the establishment which on 10 Single-use Devices					

Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**7 Document Control**			
Status	**Audit Criteria**			
Comply	i.	Document Control	The establishment shall control the documents required by the GDPMD regulatory compliance system and establish a documented procedure for the control of documents.	
Comply	ii.	Document Authorization	All documents shall be prepared, approved, signed, and dated by an authorized person.	
Comply	iii.	Appropriate authorization for change	The establishment shall give appropriate authorization on any change on authorized person permitted to carry out the task in sub- clause (ii).	
Comply	iv.	Superseded Document Control	When a document has been revised, the control system shall prevent unintended use of the superseded version.	
Comply	v.	Record Management	The establishment shall establish and maintain records that are legible, readily identifiable, retrievable, and establish a documented procedure for the control of records.	
Comply	vi.	Record Retention	The establishment shall retain records for a specific period: a. as per regulatory requirements, or b. equivalent to the lifetime of the medical device product, or c. no less than two years from the shipment date of the medical device, whichever is the longest.	
Evidence				
i. NMS-P01 Document Control, rev. 0, eff. 01/08/2024 ii. NMS-P01 Control of Records, rev. 0, eff. 01/08/2024 iii. There are 3-tier of GDPMD documentation a. Manual b. Procedure c. Forms iv. Procedures Master List - 18 procedures with internal document being prepared by DP and approved by MD v. Records Master List/ Record Retention Table - 25 forms while retention period defined at minimum 2 years vi. Storage of records: Document in hardcopy version vii. Protection of records: There is only 1 Master Copy, physical version while, there is NIL distribution being made. If there is any, it will be flagged as uncontrolled copy				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**8 Responsibilities and Authorities**			
Status	**Audit Criteria**			
Comply	i.	Responsibilities and Authorities are defined, documented, and communicated	The establishment shall ensure that responsibilities and authorities are defined, documented, and communicated within the establishment.	
Comply	ii.	Interrelation and Independence of Personnel	The establishment shall establish the interrelation between all personnel who manage, perform and verify works that affect the quality, safety, and performance of the medical device and ensure independence and authority to perform these tasks.	
Evidence				
a. NMS-F23 Organization Chart, rev. 0, eff. 01/08/2024 consist of Chairman, Director, Senior Manager (Finance & Administration), Senior Executive (Finance & Administration), Business Development Manager, Sales (Operation Executive) b. NMS-F22 Job Description (JD), eff. 01/08/2024 for each defined positions descriptions outline regulatory				

c. RCM-QP-NMS Quality Policy, eff. 01/08/2024 approved by MD, whereas focus on meeting with customer requirement, complying with standard and regulatory requirement while comitment towards continuous improvement		
Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**9 Designated Person**				
Status	**Audit Criteria**				
Comply	i.	Designated Person Appointment	The establishment shall appoint a designated person with defined responsibilities and authorities.		
Comply	ii.	System Establishment and Maintenance	The designated person shall ensure the GDPMD regulatory compliance system is established, implemented, and maintained.		
Comply	iii.	Reporting to Top Management	The designated person shall report to top management on the performance of the GDPMD regulatory compliance system and correct deviations.		
Comply	iv.	Regulatory Awareness	The designated person shall ensure awareness of obligations to comply with regulatory requirements throughout the establishment and supply-chain.		
Comply	v.	External Liaison	The designated person shall liaise with external parties on matters relating to the Malaysian medical device regulatory requirements.		
Evidence					
i. Ms Jessica Yeoh Pek Hoon has been appointed as Designated Person effective 01/08/2024 as per Letter of Appointment approved by Director, Dato' Yap Kon Min ii. Responsibility to ensure GDPMD regulatory compliance system is maintained and established, implemented, to report to the top management on the performance of GDPMD Regulatory Compliance System, ensuring awareness on obligations to comply with regulatory requirements, etc. iii. Designated Person, Jessica Yeoh a. having experience in healthcare industry including medical device and laboratory for more than 5 years, currently working with Fomema Global Sdn Bhd as well b. having fair knowledge on GDPMD and regulatory requirement related to medical device whilst currently being assisted by medical device consultant					
Remark	NA				
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.			
	☐	Actions are needed to conform to requirements. See FINDINGS LIST			
	☐	The clause is excluded			

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**10, 11, 12 Management Review, Review input and Review output**				
Status	**Audit Criteria**				
	Management Review				
Comply	i.	Management Review	Management shall review the GDPMD regulatory compliance system at planned intervals to ensure compliance with Malaysian medical device regulatory requirements.		
Comply	ii.	Compliance Assessment and Need for Changes	The review shall include an assessment of the status of compliance and the need for changes.		
Comply	iii.	Record Keeping of Management Reviews	Management shall maintain records of these reviews.		
	Review Input				
Comply	i.	Audit Results	The input for management review shall include results of internal and external audits.		
Comply	ii.	Customer Complaints/Feedback	The review shall consider customer complaints/feedback.		
Comply	iii.	GDPMD and Medical Device Compliance	The input shall include an evaluation of GDPMD regulatory compliance system and medical device compliance.		
Comply	iv.	Surveillance and Vigilance Activities	Surveillance and vigilance activities, including field safety corrective actions, advisory notes, recalls, and adverse event/incident reporting shall be included in the review.		

Comply	v.	Manufacturer Feedback	The review shall include feedback from the manufacturer.
Comply	vi.	Authority Feedback and Directives	The input shall include feedback and directives from the Authority.
Comply	vii.	Status of Preventive and Corrective Actions	The review shall consider the status of preventive and corrective actions.
Comply	viii.	Actions from Previous Reviews	The input shall include follow-up actions from previous management reviews.
Comply	ix.	Changes Affecting the System	The review shall consider changes that could affect the GDPMD regulatory compliance system.
Comply	x.	Recommendations for Compliance	The input shall include recommendations for compliance.
	Review Output		
Comply	i.	Corrective and Preventive Actions	The output from the management review shall include decisions and actions related to required corrective and preventive actions.
Comply	ii.	Effectiveness and Compliance	The review output shall address the effectiveness of the GDPMD regulatory compliance system and its compliance with Malaysian medical device regulatory requirements.
Comply	iii.	Resource Needs	The output shall include decisions related to resource needs.
Evidence			
i. NMS-P17 Management Review, rev. 0, eff. 01/08/2024 ii. The company's management review has been conducted on annual basis iii. The 1st management review meeting as per GDPMD requirement was held on 20/08/2024, chaired by Director with participation from Designated Person/ Business Development Manager, Senior Manager, Senior Executive and Internal Auditor iii. Mandatory agenda on input and output are well-discussed including necessary action needed iv. Meeting minutes available for review			
Remark	NA		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**13 Personnel; 14 Training, Competency and Awareness**			
Status	**Audit Criteria**			
	13 Personnel			
Comply	i.	Competency of Key Personnel	Key personnel managing activities/operations shall be competent and possess appropriate professional knowledge, education, training, skills, and experience.	
Comply	ii.	Skills of Post-Market Technical Support Personnel	Skills of personnel providing post-market technical support for active medical devices shall conform to the requirements and/or standards recognized by the Authority.	
Comply	iii.	Adequate Number of Competent Personnel	The establishment shall have an adequate number of competent personnel involved in all activities/operations in the supply-chain of medical devices.	
	14 Training, Competency and Awareness			
Comply	i.	Competence Determination	The establishment shall determine the necessary competence for key personnel.	
Comply	ii.	Training Provision	The establishment shall provide training to meet identified competency needs.	
Comply	iii.	Training Effectiveness Evaluation	The establishment shall evaluate the effectiveness of the training provided.	
Comply	iv.	Records of Education, Training, Skills, and Experience	The establishment shall maintain records of education, training, skills, and experience for key personnel.	
Evidence				
i. NMS-P14 Training Procedure, rev. 0, eff. 01/08/2024 ii. Currently having total of 5 personnel in charge of overall GDPMD related activities a. Chairman - Tengku Abu Bakar Ahmad Bin Tengku Abdullah b. Director - Dato' Yap Kon Min c. Business Development Manager - Jessica Yeoh Pek Hoon d. Senior Manager - Eyvon Tan Mooi Chong e. Senior Executive - Chin Pit Fui				

iii. There is planning to conduct GDPMD Implementation Coaching on 15/10/2024. NIL training conducted at point of review. This will be verified during next assessment		
Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**15 Infrasructure**			
Status	**Audit Criteria**			
Comply	i.	Infrastructure Provision	The establishment shall determine, provide, and maintain the necessary infrastructure, including buildings, tools, and supporting services.	
Comply	ii.	Premises and Equipment Suitability	The establishment shall ensure that the premises and equipment used are suitable, secure, safe, and adequate.	
Comply	iii.	Maintenance Requirements Documentation	The establishment shall document requirements for maintaining the premises and equipment.	
Comply	iv.	Maintenance Records	The establishment shall maintain records of maintenance activities.	
Evidence				
i. NMS-P15 Cleanliness, Pest Control and Infrastructure Mangement, rev. 0, eff. 01/08/2024 ii. There are only presence of general infrastructure i.e. air conditioner and fire extinguisher				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**16 Work Environment**			
Status	**Audit Criteria**			
Comply	i.	Work Environment Management	The establishment shall determine and manage the work environment to achieve conformity to regulatory requirements.	
Comply	ii.	Health, Cleanliness, and Clothing Requirements	The establishment shall establish requirements for health, cleanliness, and clothing of personnel if their contact could affect the quality of the medical devices.	
Comply	iii.	Work Environment Conditions Monitoring and Control	The establishment shall establish procedures to monitor and control work environment conditions.	
NA	iv.	Training for Special Environmental Conditions	The establishment shall ensure all personnel working temporarily under special conditions are trained or supervised.	
Comply	v.	Control of Contaminated or Potentially Contaminated Items	The establishment shall establish special arrangements for controlling contaminated or potentially contaminated medical devices, work environment, or personnel.	
Evidence				
i. NMS-P15 Cleanliness, Pest Control and Infrastructure Mangement, rev. 0, eff. 01/08/2024 ii. Goods only need to be stored at ambient/ room temperature. However, the company not intend to store any goods in premise whereas will only proceed with purchase activities later upon order by customer while the goods will be sent directly to customer				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**17 Cleanliness and Pest Control**			
Status	**Audit Criteria**			
Comply	i.	Cleanliness of Premises	The establishment shall establish requirements for cleaning premises, including frequency and methods, and maintain records of cleaning.	

Comply	ii.	Pest Control	The establishment shall establish a pest control program to identify and prevent pest infestation, and maintain records of the pest control program.
Evidence			
i. NMS-P15 Cleanliness, Pest Control and Infrastructure Mangement, rev. 0, eff. 01/08/2024 ii. The premise has maintained its cleanliness with NIL infestation of pest			
Remark	NA		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**18 Authorization**				
Status	**Audit Criteria**				
Comply	i.	Authorization	The establishment shall obtain appropriate authorization to become an authorized representative, importer, or distributor of medical devices.		
Comply	ii.	Written Agreement	The establishment shall establish and maintain written agreement with the relevant party concerning the supply of information required for regulatory matters relating to the medical devices it deals with.		
Evidence					
i. Nexgen Medsolutions Sdn. Bhd. has received authorization via Letter of Authorization as Distributor from a. Pentavest Holdings Sdn. Bhd., Melaka, 19/07/2024, signed by Managing Director. Details information as per Annex 3 of this Audit Report ii. Latest supporting documents i.e ISO 13485:2016 Certificate, Establishment License, etc have been retained in ensuring compliance against local regulatory requirement a. ISO 13485:2016 no. MD-QMS/91/R/I/2799 issued by Zenith Quality Assessors Pvt Ltd, expires on 16/06/2025 b. Establishment License no. MDA--3476-K122 expires on 19/04/2025 as Manufacturer					
Remark	OBS 2: To request copy of latest ISO 13485:2016 Certificate from Pentavest Holdings Sdn Bhd issued by local Conformity Assessment Body registered with Medical Device Authority				
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.			
	☐	Actions are needed to conform to requirements. See FINDINGS LIST			
	☐	The clause is excluded			

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**19 Communication Channels**				
Status	**Audit Criteria**				
Comply	i.	Communication Channels	The establishment shall establish and maintain communication channels and feedback mechanisms to disseminate all relevant and updated medical device information to related parties effectively.		
Comply	ii.	Managing Communication	The establishment shall manage and communicate with users, public and Authority on matters pertaining to medical devices it deals with.		
Comply	iii.	Communication with Manufacturers	The establishment shall establish efficient communication channels with the manufacturers for the effective dissemination of all relevant medical device information to the related Effectively.		
Comply	iv.	Feedback Mechanism	The establishment shall establish a feedback mechanism for collecting comments and complaints from users and the public, to be forwarded to the relevant party as applicable.		

Comply	v.	Information on Maintenance Services	As applicable, the establishment shall establish a mechanism to provide information on maintenance services, including calibration, provision of spare parts and other services, to the users.

Evidence

i. NMS-P06 Customer Enquiry, Sales and Order Processing, rev. 0, eff. 01/08/2024
ii. The company has established communication and feedback mechanisms with its principal, the manufacturer, the Authority, the user, and the public to ensure relevant information is shared, complaints or feedback are collected, and services are provided as applicable.
a. internal (staff) - email, WhatsApp application, phone call, meeting, etc.
b. external (supplier, customer, authority) - email, letter, PO, DO, Invoice, etc
iii. Communication records on field safety corrective actions (FSCAs), field safety notices (FSNs), recalls, and mandatory problem reporting to all relevant parties
a. established related forms in accordance with local regulatory requirement
b. NIL PMS case available

Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**20 Receipt of Stock**			
Status	**Audit Criteria**			
NA	i.	Inspection of Received Medical Devices	The establishment shall establish and implement inspection or other activities necessary to ensure that received medical devices meet the specified requirements.	
Comply	ii.	Verification Records	The establishment shall maintain records of verification.	

Evidence

i. NMS-P07 Storage and Delivery, rev. 0, eff. 01/08/2024
ii. NMS-P08 Purchasing, rev. 0, eff. 01/08/2024
iii. NMS-P09 Control of Supplier, rev. 0, eff. 01/08/2024
iv. The goods will be sent directly to customer upon order
v. The company will maintain traceability records i.e. PO, DO, Invoice, etc for traceability purpose

Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	NA
Clause	**21 Storage and Stock Handling**			
Status	**Audit Criteria**			
NA	i.	Storage Measures	The establishment shall identify storage measures for specific medical devices and store them in accordance with the manufacturer's instructions.	
NA	ii.	Adequate Storage	The establishment shall provide suitable and adequate storage to ensure proper conservation of the medical devices.	
NA	iii.	Updated Distribution Records	The establishment shall maintain an updated distribution records of medical devices it deals with, including the make, model, batch number, serial number, and quantity of the devices, as appropriate.	
NA	iv.	Precautions Against Deterioration or Damage	The establishment shall establish adequate precautions and control to prevent deterioration or damage of the medical devices.	
NA	v.	Quarantine Measures	The establishment shall ensure that quarantined areas are clearly marked and accessible only to authorized personnel.	
NA	vi.	System Replacing Physical Quarantine	Any system replacing physical quarantine shall provide equivalent security.	
NA	vii.	Special Risk Medical Device Storage	Medical devices presenting special risks of abuse, fire or explosion should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.	
NA	viii.	Broken or Damaged Medical Device	Broken or damaged medical device should be identified and withdrawn from usable stock and stored separately.	

Evidence		
Excluded and found to be justified		
Remark	NA	
Statement concerning conformity	☐	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☒	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	NA
Clause	**22 Stock Rotation**			
Status	**Audit Criteria**			
NA	i.	Stock Rotation	The establishment shall establish a system to ensure stock rotation.	
NA	ii.	Separation of Expired Devices	The establishment shall separate medical devices beyond their expiry date or shelf life from usable stock and label them clearly.	
NA	iii.	Disposal of Expired Devices	The establishment shall dispose of the expired medical devices in accordance with clause 25.	
Evidence				
Excluded and found to be justified				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☒	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**23 Delivery to Customer**			
Status	**Audit Criteria**			
Comply	i.	Verification of Device Documentation	The establishment shall verify that the registered medical device is accompanied by certificate of registration, license and other applicable documents and instructions for use.	
Comply	ii.	Device Identification	The establishment shall ensure that the medical device bears type, batch or lot number, model and serial number or other elements of identification as well as name, trade name and address of the manufacturer and/or distributor organization.	
Comply	iii.	Compliance with Regulatory Requirements	The establishment shall only sell and/or distribute designated medical devices to persons or entities entitled to acquire such devices as specified by regulatory requirement by obtaining the proof of such authority prior to the distribution of medical devices to such person	
Comply	iv.	Documentation of Supplies	The establishment shall provide documentation of all medical devices supplied to customers to ascertains: i. the date ii. the name of the medical device iii. the quantity supplied iv. the batch or lot number and/or model and serial number and the name; and address of the distributor and addressee	
Comply	v.	Record Keeping	The establishment shall keep a record of delivery transactions as the proof of medical devices supplied to customers	
Comply	vi.	Provision of Manufacturer's Information	The establishment shall obtain all relevant conditions for storage, transportation, installation, testing and commissioning requirements, user and service manuals, spare parts list and relevant certificates from the manufacturer and provide to the customer.	
Comply	vii.	Compliance with Delivery Conditions	The establishment shall ensure the delivery of medical devices adheres to the conditions specified by the manufacturer.	
Comply	viii.	Safe and Secure Delivery	The establishment shall establish adequate and specialized methods of delivery to achieve safe and secure delivery of the medical device from the point of collection to the point of delivery	
NA	ix.	Special Care for High-Risk Devices	The establishment shall ensure that medical devices which present special risks of abuse, fire or explosion are stored and transported in safe, dedicated, secure areas and containers and vehicles, and comply with the applicable regulatory and/or statutory requirements.	

Evidence		
i. NMS-P07 Storage and Delivery, rev. 0, eff. 01/08/2024 ii. The goods will be delivered directly by supplier to customer while any inspection activities will be fulfilled by supplier accordingly iii. The company will maintained PO, DO, Invoice, etc for traceability purpose		
Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**24 Control of Nonconforming Medical Devices including Returned Medical Devices**			
Status	**Audit Criteria**			
Comply	i.	Handling of Returned Devices	The establishment shall establish documented procedures for handling of returned medical devices.	
Comply	ii.	Control of Nonconforming Devices	The establishment shall ensure that medical devices which do not conform to essential safety and performance principles are identified and controlled.	
Comply	iii.	Documented Control Procedures	The establishment shall define controls, related responsibilities, and authorities for dealing with nonconforming medical devices in a documented procedure.	
Comply	iv.	Nonconforming Product Handling	The establishment shall deal with nonconforming products by taking action to eliminate the nonconformity or authorizing its delivery and use under concession.	
Comply	v.	Concession Compliance	The establishment shall ensure that nonconforming medical devices are delivered and used by concession only if regulatory requirements are met.	
Comply	vi.	Concession Authorization	The establishment shall maintain records of the justification and identity of the person(s) authorizing the concession.	
Comply	vii.	Nonconformity Records	The establishment shall maintain records of the nature of nonconformities and any subsequent actions taken.	
Comply	viii.	Post-Delivery Actions	The establishment shall take action appropriate to the effects, or potential effects, of the nonconformity, when nonconforming product is detected after delivery.	
Evidence				
i. NMS-P05 Non Conforming Medical Device, rev. 0, eff. 01/08/2024 ii. There is NIL nonconformity at point of review. If there is any, it will be further communicated with supplier for further action				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**25 Disposal of Medical Devices**			
Status	**Audit Criteria**			
Comply	i.	Procedure for Disposal	The establishment shall establish a documented procedure for the disposal of medical devices in accordance with regulatory requirements and any other applicable statutory requirements.	
Comply	ii.	Segregation of Devices for Disposal	The establishment shall ensure that medical devices not immediately sent for disposal are kept in a clearly segregated, safe, and secured area and identified in accordance with regulatory requirements and any other applicable statutory requirement.	
Comply	iii.	Disposal Records	The establishment shall maintain records of the disposal.	
Evidence				
i. NMS-P10 Disposal of Medical Device, rev. 0, eff. 01/08/2024 ii. There is NIL disposal at point of review				

Remark	NA	
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☐	The clause is excluded

Auditor	Daniel Manaf	**Auditee Name**	Jessica Yeoh
Clause	**26 Traceability; 39 Distribution Records**		
Status	**Audit Criteria**		
	26 Traceability		
Comply	i.	Record Keeping for Traceability	The establishment shall maintain updated records providing traceability of medical devices throughout the supply-chain being dealt with, which include the make, model, batch number, serial number, and quantity of devices, as appropriate.
Comply	ii.	Record Retention	The establishment shall retain the records for a period of time— a. specified by relevant regulatory requirements; or b. at least equivalent to the lifetime of the medical device as defined by the manufacturer of the medical devices; or c. no less than two years from the date that the medical device is shipped from the establishment, whichever is the longest.
Comply	39 Distribution Records		
Comply	i.	Identification of Parties in Supply Chain	The establishment shall ensure all parties involved in the supply-chain are identifiable.
Comply	ii.	Measures for Traceability	The establishment shall establish measures to ensure traceability of the medical device throughout distribution channels from the manufacturer/importer to the customer and to the patient.
Comply	iii.	Secure Distribution Documentation	Records including expiry dates and batch records should be part of a secure distribution documentation enabling traceability.
Comply	iv.	Documentation of Distribution Activities	The establishment must document all activities relating to the distribution of medical devices including all applicable receipts, storage, delivery, and disposal.
Comply	v.	Detailed Distribution Records	The records must contain at least: i. the name, address, email, and phone number of the manufacturer, authorized representative, importer, exporter, distributor, and customer of the device where appropriate. ii. It should also include the name of the device, its class, and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family, or medical device group family.
Evidence			
i. NMS-P02 Control of Records, rev. 0, eff. 01/08/2024 ii. Records related to medical device will be maintained minimum 2 years iii. Stock Card, DO, Invoice, etc., will be used for traceability purpose			
Remark	NA		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

Auditor	Daniel Manaf		**Auditee Name**	NA
Clause	**27 Specific Traceability Requirements for Implantable Medical Devices**			
Status	**Audit Criteria**			
NA	i.	Tracking Record for High-Risk Implants	The establishment shall establish a tracking record for all implants especially the following high-risk medical devices down to patient level: a. mechanical heart valves, b. implantable pacemakers, their electrodes and leads c. implantable defibrillators, their electrodes and leads d. implantable ventricular support systems, e. and implantable drug infusion systems.	
NA	ii.	Tracking for Individual Medical Devices	If tracking is not possible for any individual medical devices (e.g. the tracking does not have the patient's consent), establishment shall still keep track of the medical devices down to: a. the healthcare facility level b. the date of the medical device was put into service or implanted into a patient, and c. the date the device permanently retired from use or for an implanted medical device, the date it was explanted.	
NA	iii.	Submission of Surveillance Reports	The establishment shall submit surveillance reports to the Authority at least once a year for all the above stated medical devices.	
Evidence				
Excluded and justified				
Remark	NA			
Statement concerning conformity	☐	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☒	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Tee Pei Yuan
Clause	**28 Specific Requirements for Active Medical Devices**			
Status	**Audit Criteria**			
NA	i.	Procedures for Active Medical Devices	The establishment shall establish and maintain documented procedures and work instructions for performing installation, testing, commissioning, and maintenance activities in accordance with Malaysian Standard MS 2058 and any other requirements specified by the Authority.	
NA	ii.	Documentation for Servicing Activities	The establishment shall establish and maintain documented procedures, work instructions and reference materials, tools and test equipment and reference measurement procedures, for performing servicing activities including calibration, repair, maintenance, and verifying that they meet regulatory requirements and applicable standards.	
NA	iii.	Installation Requirements & Qualification	The establishment shall establish documented requirements containing acceptance criteria for installation, testing, and commissioning of the medical device and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements.	
NA	iv.	Equipment Calibration & Verification	The establishment shall ensure that equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals, and conforms to the applicable standards.	
NA	v.	Record Maintenance	The establishment shall maintain testing and commissioning, installation, calibration, and maintenance service records.	
NA	vi.	Technical Support Establishment	The establishment shall establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management, and a maintenance management mechanism to support customers, in accordance with applicable regulatory requirements.	
Evidence				
Excluded and justified. There is establishment of SOP as per ESC-P14 Active Medical Devices, rev. 0, eff. 01/04/2024				
Remark	NA			

Statement concerning conformity	☐	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.
	☐	Actions are needed to conform to requirements. See FINDINGS LIST
	☒	The clause is excluded

Auditor	Daniel Manaf		**Auditee Name**	NA
Clause	**29 Outsourced Activities**			
Status	**Audit Criteria**			
NA	i.	Control over Outsourced Processes	The establishment shall ensure control over outsourced processes within the scope of GDPMD.	
NA	ii.	Ensuring Conformance	The establishment shall establish requirements to ensure that the outsourced activities conform to specified requirements.	
NA	iii.	Control Based on Impact	The establishment shall ensure the type and extent of control applied to the supplier are dependent on the impact on meeting the requirements of GDPMD.	
NA	iv.	Auditing Outsourced Activities	The establishment shall ensure that for outsourced activities, the supplier is audited as part of the establishment's system unless the supplier is already certified to GDPMD covering the scope of the outsourced activities.	
NA	v.	Written Agreements	The establishment shall develop written agreements with the outsourced party to ensure that appropriate measures are taken to safeguard the safety and performance of the medical devices, including maintaining appropriate documentation and records, and these agreements should comply with regulatory requirements and any relevant statutory requirements.	
NA	vi.	Maintaining Responsibility	The establishment is not absolved of the responsibility of conformity to GDPMD, statutory and regulatory requirements despite control over outsourced processes.	
Evidence				
Excluded and found to be justified				
Remark	NA			
Statement concerning conformity	☐	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☒	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**30 Counterfeit, Adulterate, Unwholesome and Tampered Medical Devices**			
Status	**Audit Criteria**			
Comply	i.	Segregation of Counterfeit Devices	Upon finding any counterfeit, adulterate, and tampered medical devices in their distribution network, the establishment shall physically segregate them from other medical devices to avoid any confusion.	
Comply	ii.	Labelling of Counterfeit Devices	The establishment shall clearly label any counterfeit, adulterate, and tampered medical devices found in the distribution network as "Not for Sale" or other similar phrases/words.	
Comply	iii.	Reporting to Authority and Manufacturer	The establishment shall inform the Authority and the manufacturer immediately upon finding any counterfeit, adulterate, and tampered devices.	
Evidence				
NIL case of counterfeit, adulterate, unwholesome or tampered medical devices at the point of review				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	NA
Clause	**31-36 Secondary Assembly including Repacking**			
Status	**Audit Criteria**			
	31 General Requirements			
NA	i.	Assembly under Controlled Conditions	The establishment shall plan and carry out secondary assembly of medical devices under controlled conditions. This includes access to relevant information, procedures, work instructions, materials, measurement procedures, equipment, monitoring devices, and appropriate implementation of activities	

NA	ii.	Traceability and Batch Records	The establishment must maintain a record for each batch of medical devices, providing traceability and identifying the quantity assembled and approved for distribution. This record should be verified and approved by qualified personnel.
	32 Assembly Documents		
NA	i.	Batch Assembly Records	The establishment shall maintain a batch assembly record for each batch or part batch assembled, detailing the batch number and the quantity of bulk medical devices to be packed.
NA	ii.	Real-Time Assembly Documentation	The assembly shall be documented in real-time, recording all significant activities concerning the assembly of the medical device.
NA	iii.	Record Retention	Records shall be retained for a time period defined by regulatory requirements, at least equivalent to the device's lifetime as defined by the product owner, or no less than two years from the shipment date from the establishment, whichever is longest.
	33 Materials Control		
NA	i.	Incoming Device Check	Ensure the integrity of package and seal, correspondence between delivery note and supplier's labels, and compliance with quality specifications for each delivery of medical devices.
NA	ii.	Use of Devices	Ensure medical devices with breached primary packages are not used for secondary assembly.
NA	iii.	Labelling and Identity Assurance	Medical devices in storage are appropriately labelled, and procedures ensure the identity of each packing's contents.
NA	iv.	Bulk Container Identification	Ensure bulk containers from which quantities of medical devices have been drawn are clearly identified.
NA	v.	Special Storage Conditions	Medical devices requiring special storage conditions are placed in appropriately equipped areas.
NA	vi.	Storage Monitoring	The storage conditions are continuously monitored and recorded.
NA	vii.	Quantitative Temperature	The actual storage temperature is expressed quantitatively.
NA	viii.	Packaging Material Control	Purchase, handling, and control of packaging materials are given similar attention as starting materials.
NA	ix.	Packaging Operation Program	Setting up a program for packaging operations to minimize the risk of cross-contamination, mix-ups or substitutions.
NA	x.	Segregation During Packaging	Different medical devices shall not be packaged in close proximity unless there is physical segregation.
	34 Labelling		
NA	i.	Original Labelling on Repackaged Devices	Ensure that repackaged medical devices bear all original labelling (including instruction for use, label, any other information sheet or leaflet, etc.)
NA	ii.	Labelling Information	All labelling information is included on repackaged devices, except for quantity and distributor identity.
	35 Good Assembly Practices		
NA	i.	Checking Medical Devices and Materials	All medical devices and materials used for assembly should be checked for quantity, identity, and conformity with packaging instructions
NA	ii.	Line Clearance	Perform line clearance prior to assembly operation commencement
NA	iii.	Printing Operations	Checking and recording of correct performance of any separate or in-course packaging printing operation
NA	iv.	Hand Printing	Regular re-checking of printing by hand
NA	v.	Assembly Equipment Cleaning and Storage	Assembly equipment/apparatus are cleaned as per detailed procedures and stored in a clean, dry condition
NA	vi.	Safety of Assembly Equipment	Assembly equipment/apparatus do not present any hazard to the medical devices
NA	vii.	Quality of Contact Parts	Parts of assembly equipment/apparatus in contact with medical devices do not affect their quality
NA	viii.	Control Equipment Calibration	Control equipment is calibrated and checked at defined intervals, records are maintained
	36 Quality Control		
NA	i.	Finished Medical Device Assessment	Assessment of finished medical devices should include all relevant factors such as assembly conditions, review of packaging documentation, compliance with finished medical device specification and visual examination of the final pack

NA	ii.	Secondary Assembly Impact	The process of secondary assembly should not compromise the conformity of the medical device to essential principles of safety and performance, as stipulated in Act 737 and its subsidiary legislations
Evidence			
Excluded and found to be justified.			
Remark	NA		
Statement concerning conformity	☐	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☒	The clause is excluded	

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**37 General; 38 Medical Device Complaints**				
Status	**Audit Criteria**				
	37 General				
Comply	i.	Monitoring Safety and Performance	The establishment shall establish and implement a documented procedure for monitoring the safety and performance of medical devices that are imported, exported and placed in the market.		
	38 Medical Device Complaints				
Comply	i.	Complaint Handling Procedure	The establishment shall establish and implement a documented procedure for handling complaints regarding medical devices.		
Comply	ii.	Complaint Review and Investigation	The establishment shall ensure all complaints and other information concerning potentially defective and counterfeit medical devices must be reviewed and thoroughly investigated. The investigation should identify the origin or reason for the complaint.		
Comply	iii.	Record Maintenance and Follow-Up Action	The establishment shall maintain records of the complaint, investigation, and any subsequent actions taken. Appropriate follow-up action should be taken after investigation and evaluation of the complaint where necessary.		
Comply	iv.	Complaint Sharing System	The establishment shall put in place a system by which the complaints, the response received from the medical device manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.		
Evidence					
i. NMS-P18 Monitoring Safety and Performance, rev. 0, eff. 01/08/2024 ii. NMS-P16 Medical Device Complaints, rev. 0, eff. 01/08/2024 iii. NIL complaint at point of review					
Remark	NA				
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.			
	☐	Actions are needed to conform to requirements. See FINDINGS LIST			
	☐	The clause is excluded			

Auditor	Daniel Manaf			**Auditee Name**	Jessica Yeoh
Clause	**40 Field Corrective Action (FCA) and Field Safety Notice (FSN)**				
Status	**Audit Criteria**				
Comply	i.	Procedures for FCA and FSN	The establishment shall establish documented procedures for the handling of FCA and FSN.		
Comply	ii.	Definition of Responsibilities	Define the responsibilities for planning, conducting, and reporting of corrective actions in the documented procedure.		
Comply	iii.	Recall or Withdrawal Procedure	Establish a written recall or withdrawal procedure in consultation with the manufacturer.		
Comply	iv.	Notification of Authority	Inform the Authority prior to execution of FCA and FSN.		
Comply	v.	Notification of Customers	Inform all customers to whom the medical device was distributed with the appropriate degree of urgency.		
Comply	vi.	Notification of Overseas Counterparts	Inform overseas counterparts on the FCA and FSN if the medical devices are exported.		
Comply	vii.	Removal and Storage of Affected Devices	Request that the affected medical devices be removed immediately from usable stock and stored separately in a secure area until they are disposed of according to manufacturers' instructions.		

Comply	viii.	Record Keeping	Maintain records of all actions taken in connection with the FCA and FSN and their approval by the manufacturer and the Authority.
Evidence			
i. NMS-P11 Field Safety Corrective Action, rev. 0, eff. 01/08/2024 ii. NIL case at point of review.			
Remark	NA		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**41 Recall**			
Status	**Audit Criteria**			
Comply	i.	Recall Procedure	The establishment shall have a documented procedure for effectively and promptly recalling medical devices that are known or suspected to be defective or counterfeit.	
Comply	ii.	Regulatory Compliance	The recall system shall comply with regulatory requirements.	
Comply	iii.	Manufacturer Notification	The manufacturer and/or authorized representative shall be informed in the event of a recall.	
Comply	iv.	Consultation before Recall	Consultation with the manufacturer and/or authorized representative shall take place before the recall is instituted, where possible.	
Comply	v.	Reporting to Authority	Recall information shall be reported to the Authority.	
Comply	vi.	Recall Progress Tracking	The progress of a recall process shall be recorded and a final report issued, including a reconciliation between delivered and recovered quantities of products.	
Evidence				
i. NMS-P12 Product Recall, rev. 0, eff. 01/08/2024 ii. NIL case at point of review.				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**42 Mandatory Problem Reporting**			
Status	**Audit Criteria**			
Comply	i.	Procedure for Incident Reporting	The establishment shall establish a documented procedure for incident/problem reporting to comply with regulatory requirements.	
Comply	ii.	Incident Identification	The procedure shall include the identification of the nature of the incident/problem.	
Comply	iii.	Investigation	The incident/problem shall be investigated.	
Comply	iv.	Evaluation and Analysis	The incident/problem shall be evaluated and analyzed.	
Comply	v.	Action Implementation	The procedure shall dictate the action to be taken post incident/problem.	
Comply	vi.	Incident Report Final Report	Each incident report shall lead to a final report where corrective actions are applicable.	
Evidence				
i. NMS-P13 Mandatory Problem Reporting, rev. 0, eff. 01/08/2024 ii. NIL case at point of review.				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**43 Internal Audit**			
Status	**Audit Criteria**			
Comply	i.	Audit Procedure	The establishment shall establish a documented procedure for planning, conducting audits, and maintaining audit records.	
Comply	ii.	Audit Planning	The establishment shall plan an audit program considering the importance of the processes and areas to be audited, and previous audits.	
Comply	iii.	Audit Criteria	The establishment shall define the audit criteria, scope, frequency, and methods.	
Comply	iv.	Internal Audits	The establishment shall conduct internal audits at planned intervals to monitor the implementation of and compliance with the GDPMD.	
Comply	v.	Audit Records	The establishment shall maintain records of the audits and their results.	
Comply	vi.	Corrective Actions	The establishment shall take actions to eliminate detected nonconformities without undue delay.	
Evidence				
i. NMS-P03 Internal Audit, rev. 0, eff. 01/08/2024 ii. Internal audit has been scheduled to be conducted once every 12 months iii. 1st Internal Audit as per GDPMD requirement was conducted on 19/08/2024 led by appointed Internal Auditor, Izzat Shafiq assisted by Jessica Yeoh a. Appointed Internal Auditor having more than 8 years of experience in medical device industry b. GDPMD Certificate Training, 15-16/12/2021 issued by MDA iv. Assessment recorded NIL finding v. Internal Audit records are available to be reviewed				
Remark	NA			
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.		
	☐	Actions are needed to conform to requirements. See FINDINGS LIST		
	☐	The clause is excluded		

Auditor	Daniel Manaf		**Auditee Name**	Jessica Yeoh
Clause	**44 Corrective Action; 45 Preventive Action**			
Status	**Audit Criteria**			
	44 Corrective Action			
Comply	i.	Corrective Action	The establishment shall take action to eliminate the cause of nonconformities to comply with GDPMD and Act 737.	
Comply	ii.	Documented Procedure	A documented procedure shall be established to define requirements for various stages of corrective action.	
Comply	iii.	Review of Nonconformities	The establishment shall review nonconformities including customer complaints.	
Comply	iv.	Cause Determination	The establishment shall determine the causes of nonconformities.	
Comply	v.	Action Evaluation	The establishment shall evaluate the need for action to ensure that nonconformities do not recur.	
Comply	vi.	Action Implementation	The establishment shall determine and implement needed actions, including updating documentation if appropriate.	
Comply	vii.	Results Recording	The establishment shall record the results of any investigation and action taken.	
Comply	viii.	Corrective Action Review	The establishment shall review the corrective action taken and its compliance with GDPMD and regulatory requirements.	
	45 Preventive Action			
Comply	i.	Preventive Action	The establishment shall determine proactive action to eliminate causes of potential nonconformities, in compliance with GDPMD and regulatory requirements.	
Comply	ii.	Documented Procedure	The establishment shall establish a documented procedure to define requirements for preventive action.	
Comply	iii.	Determining Potential Nonconformities	The procedure shall include steps for determining potential nonconformities and their causes.	
Comply	iv.	Evaluating Preventive Action Need	The procedure shall include steps for evaluating the need for action to prevent nonconformity occurrence.	
Comply	v.	Implementing Preventive Action	The procedure shall include steps for determining and implementing needed action.	
Comply	vi.	Recording Investigation Results	The procedure shall include steps for recording the results of investigations and actions taken.	

Comply	vii.	Reviewing Preventive Action	The procedure shall include steps for reviewing preventive action taken and its effectiveness.
Evidence			
i. NMS-P04 Corrective and Preventive Action, rev. 0, eff. 01/08/2024 iii. NIL issuance of CAPA/ CAR			
Remark	NA		
Statement concerning conformity	☒	Based on objective evidence reviewed this section is effectively implemented and conforms with requirements.	
	☐	Actions are needed to conform to requirements. See FINDINGS LIST	
	☐	The clause is excluded	

5. Statement on the Conformity and the Effectiveness of the Regulatory Compliance System

Remarks	Satisfactory to Grant Certification/ Certification Maintenance?	
	Yes	**No**
Evidence is available to demonstrate the capability of the regulatory compliance system to adhere to GDPMD standard and deemed satisfactory	☒	☐
Evidence related to the internal audit and management review process is available to substantiate its due process and fulfillment	☒	☐
Certification scope is appropriate for the regulatory compliance system	☒	☐
The audit objectives have been fulfilled based on audit findings	☒	☐
Recommendation for certification/ certification maintenance	☒	☐

6. List of Devices Dealt with by the Establishment

TICK	No	Device Category
	01	Active implantable devices
	02	02 Anesthetic and respiratory devices
	03	03 Dental Devices
	04	04 Electro mechanical medical devices
	05	05 Hospital hardware
	06	06 In vitro diagnostic devices
	07	07 Non-active implantable devices
	08	08 Ophthalmic and optical devices
	09	09 Reusable devices
√	**10**	Single-use devices
	11	Assistive products for persons with disability
	12	Diagnostic and therapeutic radiation devices
	13	Complementary therapy devices
	14	Biologically-derived devices
	15	Healthcare facility products and adaptations
	16	Laboratory equipment
	17	Medical software
	18	Others: PLEASE SPECIFY

7. Certification Decision

Remarks	Certification Decision
Based on the findings of the audit and the assessment of the organization's compliance with the GDPMD standard and regulatory requirements and the satisfaction of the assessment, it is recommended for -	**GRANTING CERTIFICATION**

	Auditor	Reviewer	Personnel Managing Programme
Name	 Daniel Manaf	 Raja Nazrel	 Ikram Redwan
Position	Lead Auditor	Technical & Certification Committee	CEO
Date	09/09/2024	11/09/2024	11/09/2024

8. Finding List

During the closing meeting, the list of audit findings was communicated to the organization's top management. During the meeting, the audit team conveyed the final conclusion of the audit results and recommendation to the management

Issues Raised		
	Type of Findings	**No. of Findings**
☐	Major NCR(s) - Major nonconformance(s) have been raised	0
☐	Minor NCR(s) - Major nonconformance(s) have been raised	0
☒	No non-conformance. No nonconformance issues have been raised	0

Non-conformance List			
NC	**Standard/ Clause No.**	**Non-conformance Category**	**Non-conformance Details**
			NA

Summary of Audit Findings
The GDPMD system is well-established, maintained and complied with GDPMD standard and regulatory requirement. There are issuance of Observations which further action needed from establishment and will be verified during next assessment #OBS 1: To revise exclusion of clause in Regulatory Compliance Manual on the outsourced activities as the declared activities on transportation to principal is not consider as outsource activity as per GDPMD standard #OBS 2: To request copy of latest ISO 13485:2016 Certificate from Pentavest Holdings Sdn Bhd issued by local Conformity Assessment Body registered with Medical Device Authority

Annex 1

Abbreviations and Acronyms

CAB	:	Conformity Assessment Body
GDPMD	:	Good Distribution Practice For Medical Device
MDA	:	Medical Device Authority
MEDCREST	:	Medical Device Centralized Reporting System
MDR	:	Medical Device Regulation
SOP	:	Standard Operating Procedure
NCR	:	Non-Conformance Report
CAR	:	Corrective Action Request
PAR	:	Preventive Action Request
RCM	:	Regulatory Compliance Manual
PO	:	Purchase Order
DP	:	Designated Person
ID	:	Identification
PPM	:	Planned Preventive Maintenance
QA	:	Quality Assurance
AR	:	Authorized Representative
JD	:	Job Description
FSCA	:	Field Safety Corrective Action
FSN	:	Field Safety Notice
DSM	:	Department of Standard Malaysia
CCTV	:	Closed-Circuit Television
AELB	:	Atomic Energy Licensing Board
ASL	:	Approved Suppliers List
CAPA	:	Corrective and Preventive Action

Annex 2

Guideline for GDPMD Auditors: A Standardized Approach to Reviewing Evidences and Preparing Audit Report.

Objective

The objective of this guideline is to establish a standardized approach for GDPMD auditors when reviewing evidences during GDPMD audits and preparing audit reports. MDA strives to ensure that audits and audit reports prepared by registered GDPMD auditors uphold consistency and quality, ultimately facilitating the presence of safe and effective medical devices in Malaysia. The audit report, along with the GDPMD certificate, must be submitted for both new and renewal establishment license applications.

Scope and Application

This guideline outlines the prescribed format and content of the audit report for GDPMD audits, as well as the recommended evidence that auditors may consider during the audit process. GDPMD auditors must adhere to the prescribed format when drafting the audit report that accompanies the GDPMD certificate issued by the CAB to the establishment.

Instructions for Using the Audit Report Format

The prescribed audit report format must be used to ensure standardization across all GDPMD audits. Auditors should follow these guidelines when using the format:

1. Do not modify the section headers or clause numbers already populated in the format. These reflect the clauses from the GDPMD standard document that auditors need to assess.
2. Ensure that the final audit report is submitted in strict adherence to the specified format, content, and structure.
3. For each clause, document evidence reviewed, status of compliance, findings, and other audit details within the provided text boxes.
4. Indicate compliance status for each clause using the provided options: Comply, Not Comply, NA.
5. When conducting the audit, ensure that all relevant clauses are thoroughly reviewed and properly marked as completed. In cases where a clause is not applicable, a justification note must be provided.
6. Should a clause is excluded, it is necessary to provide a clear and understandable justification that explain the rationale for its exclusion
7. The statement of conformity should effectively summarize the audit findings and offer a definitive recommendation on certification, supported by the evidence examined.
8. Lists of nonconformities should be included in the findings attached with the report.

Documenting Audit Evidence

When recording examination of audit evidence within the report, auditors must ensure proper version control and traceability back to the original artifact, record or document. Please adhere to these notations:

1. Quote the document ID number, title, date, and revision/version
2. For example, " Inspection Checklist (FORM-076 v3 dated 5 Jan 2022)"
3. When quoting a printed record, include the unique record number or identifier along with record title, date etc.
4. For example: "CAPA Record #0451 raised on 12 Dec 2022"
5. For electronic records such as digital SOP copies or database entries, include filename, system details and timestamps
6. "Complaints Log from MEDCREST database. Entry #14971 created on 05 Jan 2023."
7. Where possible, take legible screenshots, photos or copies of the actual record/evidence and insert within the remark section of related GDPMD clause. / put as attachment

By incorporating specific references, traceability markers, and attachments, the authenticity of the audited evidence can be established, as it confirms that it was directly assessed during the audit. By enabling readers to pinpoint specific evidence files, this ensures that more details can be accessed later if necessary.

Annex 3

List of Letter of Authorization for Establishment

No.	Manufacturer / Supplier Name	Role (AR / Importer / Distributor)	Medical Device Category	Date of LOA
1	Pentavest Holdings Sdn. Bhd.	Distributor	Single Use Device • Nano Antimicrobial Nitrile Gloves (Pentanano) • Nitrile Examination Powder Free Gloves (Penta Glove) • Latex Examination Powder Free Gloves (Penta Glove)	19/07/2024

Annex 4

GDPMD Provisional Certification

This GDPMD Provisional Certification applies to all new establishments involved in the distribution of medical devices within the jurisdiction governed by the Medical Device Act 2012 (Act 737), Medical Device Regulations 2012 (P.U. (A) 500), and Regulatory Requirements (MDA/RR No. 1 November 2015 First Revision), where a Provisional GDPMD Certificate will be issued by Conformity Assessment Body (CAB).

Audit Process:

1. CAB will conduct an audit of the establishment's facilities, procedures, and documentation to assess compliance with GDPMD requirements.
2. The audit will focus on elements outlined in MDA/RR No. 1 November 2015 First Revision, including but not limited to the Regulatory Compliance Manual (RCM), documented procedures, and readiness assessment (facility's compliance, including the out-sourced activities, resources, and listing of potential medical devices).
3. Excluded elements such as records of implementation, management review, internal audit, and post-market surveillance activity may not be audited.

Certification Issuance:

1. Upon successful completion of the audit, the CAB will issue a Provisional GDPMD Certificate to the establishment.
2. The certificate will be valid for 12 months (1 year) from the date of issuance.
3. A disclaimer shall be included in the certificate, stating that the certification is provisional and subject to the condition that the medical device(s) mentioned within are registered and fulfill all certification requirements.

Compliance Monitoring:

1. The establishment shall ensure ongoing compliance with GDPMD requirements throughout the validity period of the provisional certificate.
2. Any changes in procedures, facilities, or medical device listings should be promptly reported to the CAB for evaluation.

Transition:

1. Prior to the expiration of the Provisional GDPMD Certificate, the establishment must pursue full certification, they must undergo a comprehensive audit covering all elements, including those previously excluded.
2. Non-compliance with this requirement may result in corrective actions, including but not limited to re-audits, suspension, or revocation of the Provisional GDPMD Certificate.
3. CAB must notify MDA on a monthly basis regarding the cancellation of any Provisional Certificates. This monthly notification enables MDA to take necessary actions, including the potential cancellation of License Certificates under the Act 737.

Annex 5

Frequently Asked Questions (FAQ)

No.	Key Idea	Question	Clarification
1	Provisional certificate	How does provisional certification work and why is it necessary?	MDA introduces a "provisional certification" pathway for new establishments without prior experience in medical device regulated activities. This certification, granted by the Conformity Assessment Body (CAB), is based on the establishment's readiness to comply with the Good Distribution Practice for Medical Devices (GDPMD) and is valid for one year. During this period, the establishment must undergo the regular certification process. If no transactions are completed within the year, the provisional certificate will not be extended. This strategy allows new establishments to demonstrate their commitment to GDPMD compliance while providing time to set up operations and obtain necessary documentation. However, a provisional certificate may not include a statement of conformity, which distinguishes it from the regular GDPMD certificate, as the establishment has not yet fully demonstrated compliance through actual regulated operations.
2	Provisional certificate II	Do CABs need to issue provisional certificates with a one-year validity to all new establishments? How do we decide whether clients need a one-year or three-year validity period for their certificate? What about establishments that have activity in the second year but no activity in the third year?	Please refer to the official letter from the Medical Device Authority, which was sent to all CABs on July 10th, 2015. The official letter is enclosed in the guideline for reference purposes.
3	Outsourced process Vs procured services	Could you provide me with some examples of outsourced processes and procured services?	Establishments can outsource processes crucial to their primary business operations, known as outsourced operations, or acquire non-essential services from external providers, called purchased services. Examples of outsourced operations include entrusting logistics and distribution to experienced providers and contracting out maintenance, calibration, and upkeep of medical devices. Purchased services, such as pest control program, involve hiring external companies to handle specific tasks that support the establishment's operations but are not critical to its core business functions.
4	Certificate and Audit Report Sharing	Is it possible for the CAB to provide a single certificate for two sister companies that are sharing the same address?	Sharing of GDPMD certificates and audit reports is not permitted. Regardless of sharing the same address, each establishment must acquire its own GDPMD certification separately. Some of the rationale behind this requirement: a. Providing a single certificate may create the perception of inappropriate sharing of information between the establishments. Accessing and certifying the management system of each establishment individually is the best approach in order to maintain transparency and impartiality. b. In cases where specific establishments face issues, such as violating sections under Act 737 or having certification suspended or revoked, the certification of other establishments will remain intact if they have separate certifications.

No.	Key Idea	Question	Clarification
5	Evidence writing format	How should the evidence stated in the evidence column be written by the CAB? Does MDA have any prescribed format at this point? Is it viable to solely rely on the pre-formatted wording outlined by the MDA?	Please consult this section within the guidelines.
6	The need to adhere strictly to evidence requirement.	Is the CAB required to strictly follow the evidence-based suggestions? Suppose the establishment lacks the suggested documents as required. However, they may possess other documentation that can serve as proof of meeting the clauses. Is that acceptable?	While it is strongly recommended for CAB to obtain audit evidence in accordance with the prescribed suggested evidence by MDA, there is ultimately a chance that the documentation provided by the establishment may not align with the evidence as suggested by MDA. In the event that this occurs, the auditors will be required to provide a detailed description of their findings in the remarks section.
7	Observation and OFI	I have observed that the guideline document only references major and minor nonconformities. What about observation and opportunity for improvement?	The MDA's guideline document for GDPMD certification focuses solely on major and minor nonconformities, without mentioning observations and opportunities for improvement. This deliberate decision streamlines the certification process and ensures that audits concentrate on identifying and addressing critical issues. Major nonconformities refer to significant deviations from GDPMD requirements that could lead to product quality and safety issues, while minor nonconformities are less severe deviations that still need to be addressed. By focusing on these nonconformities, the MDA maintains a high standard of compliance among medical device establishments while keeping the certification process efficient. Although observations and opportunities for improvement can provide valuable insights for establishments to enhance their processes beyond the minimum regulatory requirements, they are not mandatory for GDPMD certification.
8	Are remarks required?	Is it necessary to add remarks in every evidence column?	As of the time of this writing, remark is not required to be written down. However, MDA retains the right to revisit this decision in case any concerns arise in the future. However, there is an exception to this rule if the specific establishment has been found to have committed non--conformities, in which case CAB is required for recording them. Nonetheless, MDA invites the CAB to provide remarks to clarify the processes and activities that may not be adequately conveyed through written evidence alone.
9	Non-standardized letter of authorization	The letter of authorization my certification client received from their foreign manufacturer/AR counterparts deviates from the prescribed format set forth by MDA. Is it acceptable for the CAB auditor to accept the non-standardized letter of authorization?	It is required to follow the prescribed template of the letter of authorization precisely. The establishments are required to refrain from omitting or inserting phrases in order to meet conditions that are not specified by the authority.
10	Requirements of reviewing letter of authorization	Does clause 18 necessitate the CAB auditor to review all the letters of authorization received by the establishment?	Yes, it is necessary for the auditor to review all of the letter of authorization received by the establishment. For the purpose of clarification, it should be noted that authorization is a mandatory requirement

No.	Key Idea	Question	Clarification
			introduced by the World Health Organization in the Medical Device Regulatory framework. The intention is to ensure that only suitably qualified establishments are chosen by the manufacturer for the distribution of medical devices, which includes having appropriate and adequate facilities, information systems, and qualified staff. This measure has been implemented to safeguard against the presence of substandard and falsified medical devices in the market. This particular requirement is being reinforced as part of the GDPMD requirement and license prerequisite and condition in the Malaysia medical device regulatory system.
11	Plug and play active medical devices	Can MDA offer illustrations of medical devices that are classified as active medical devices, but are not subject to installation, testing, commissioning, and maintenance procedures as per requirements outlined in Clause 28?	In general, most medical devices intended for home use can be used without any additional installation, testing, commissioning, or maintenance requirements. Among the devices in this category are pulse oximeters, glucometers, blood pressure monitors, nebulizers, and digital thermometers Certain medical devices, like imaging equipment such as X-Ray machines and MRI scanners, need to undergo precise calibration in order to produce accurate results. The process of installation, testing and commissioning is crucial in ensuring the Equipment's suitability for clinical use. On the other hand, maintenance requirements ensure optimal equipment operation, minimizing downtime and costly repairs. The medical devices that are most commonly required for these procedures are intended for professional use in healthcare settings Please consult the manufacturer's specification documents to obtain clarification on these requirements.
12	The need to audit outsource processes	Does the CAB auditor need to audit external companies conducting outsourced processes as per GDPMD requirements?	In the case that the outsourced party is not certified with GDPMD, it is recommended for the establishment to conduct a supplier audit on them, where necessary. The purpose of this is to ensure that the outsourced activities is in compliance with GDPMD requirements. (Evidence of services must be provided to auditors during GDPMD audits. This include written agreement, activity logs that covers whatever outsource activities that has been done)
13	E-Signature	Can put electronic signature on or just relying on physical signature?	Yes, electronic signatures can be used in place of physical signatures for GDPMD certification, provided that the electronic signature mimics the individual's real signature. This means that the electronic signature should closely resemble the person's handwritten signature, serving as a visual representation of their consent and approval.
14	Signature requirements	Does the inclusion of reviewer and personnel managing program signatures in the report mean that the report will be provided to the client only after the CAB's certification decision, and not immediately after the audit is conducted? Can we include the client's signature to prove that they have gone through the audit report?	The decision to share the audit report after the audit is completed is ultimately up to the CABs. However, for the purpose of applying to MDA, it is necessary that the audit report is complete and signed by all corresponding personnel. MDA does not perceive any issues with CABs adding the client signature to the audit report.

No.	Key Idea	Question	Clarification
15	Installation testing commissioning and maintenance requirement for plug and play active medical devices	For plug-and-play active medical devices where ITC and maintenance are not applicable, can the scope be excluded even though the device falls under the active medical device category? Do establishments still need to establish the procedure in this case?	The requirements outlined in Clause 28 pertain specifically to active medical devices, and no establishment dealing with such devices can exempt themselves from Clause 28, regardless of the devices' nature. If the establishment does not deal with active medical devices requiring ITC, auditors can indicate the subclauses as not applicable and provide an explanation in the remarks section clarifying that the establishment does not handle medical devices that require ITC.