ACCREDITATION SCHEME FOR
MANAGEMENT SYSTEMS CERTIFICATION BODIES

CT 04

SAC CRITERIA FOR CERTIFICATION BODIES (GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES)

CT 04, 29 March 2019
The SAC Accreditation Programme is managed by Entreprise Singapore

CONTENTS

1 Introduction

1.1 This document specifies the supplementary SAC criteria for the certification of Good Distribution Practice for Medical Devices (GDPMDS), and is to be used with ISO/IEC 17021-1.

2 Qualification Criteria for GDPMDS Auditors

2.1 A certification body shall appoint qualified QMS auditors to conduct GDPMDS audits.

2.2 In addition, all auditors shall have attended a briefing on the requirements of SS 620 *Good Distribution Practice for Medical Devices - Requirements* or HSA TS-01: *Good Distribution Practice for Medical Devices- Requirements*[1] and familiarised with other related HSA documents which includes GN-01: *Guidance on the Application of Good Distribution Practice for Medical Devices*, GN-03: *Guidance on Preparation of a Site Master File For Licensing* and GN-33: *Guidance on the Application of Singapore Standard Good Distribution Practice for Medical Devices*, by suitably qualified staff.

3 Requirements for Certification of GDPMDS

3.1 Stage 1 audit

A full Stage 1 audit is not required. Only the management system documentation has to be reviewed. This can be done at the certification body's premises.

3.2 Audit time

3.2.1 A minimum of 1 auditor day (8 hours) on-site is required for each initial certification, surveillance and recertification audits.

3.2.2 Additional auditor day(s) shall be required if a client has a wide range of medical devices, large number of staff, a large number of sites or complex operations. The certification body shall justify the time spent on the audits.

[1] Certified companies will be given 3-year transition period, from 9 November 2017 to 8 November 2020, to transit from HSA TS-01 Revision 2.1 to SS 620:2016.

3.2.3 The audit time could be reduced as shown below:

Type of clients	% reduction
Clients which are certified to ISO 9001 by a SAC accredited certification body for QMS (Full GDPMDS scope is not accredited)	15%
Clients which are certified to ISO 9001 by a SAC accredited certification body for QMS with the full GDPMDS scope which covers • other wholesale • storage and warehousing • other supporting land transport activities	25%

3.3 Frequency of surveillance audits

The certification body shall conduct surveillance audits on certified clients at least once a year.

3.4 Surveillance activities

The activities to be audited during each surveillance shall be the same as those activities for the quality management system certification.

3.5 Sampling of sites

The sampling of sites for audits shall be based on IAF MD 1 – IAF Mandatory Document for the Certification of Multiple Sites on Sampling.

3.6 Sampling of outsourced service providers

3.6.1 This situation applies to companies who use outsourced service providers that are not certified by SAC accredited certification bodies for GDPMDS certification or those that are not certified to ISO 13485 (Medical devices -- Quality management systems -- Requirements for regulatory purposes),

The scope of the GDPMDS certification should cover the relevant outsourced activities as follows:

- Storage
- Distribution
- Secondary assembly

3.6.2 For initial certification, all locations of the outsourced activities for storage and secondary assembly that are not GDPMDS or ISO13485 certified shall be audited.

3.6.3 During the 3-year certification cycle, all locations of the outsourced activities for storage and secondary assembly shall be audited at least once. The number of such locations shall be evenly distributed over the 3-year cycle.

3.6.4 After getting certified, new outsourced service providers or new / additional locations of existing outsourced service providers shall be audited before they can be included. Thereafter, these locations shall be audited as indicated in paragraph 3.6.3.

3.7 Report Format

Please see Annex 1 for sample report format.

Annex 1

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMDS) AUDIT REPORT

This document should be type-written.

Date of Revision: December 2017

PART I: SUMMARY

<table>
<tr><th colspan="3">SECTION A: AUDITEE INFORMATION</th></tr>
<tr><td>Company Name</td><td colspan="2"></td></tr>
<tr><td>Business Address</td><td colspan="2">Please insert location details of the business address.

Is this an audit site? ☐Y ☐N
If ‘N’ is selected, is the site GDPMDS/ISO13485 certified?
☐Y ☐N</td></tr>
<tr><td>Address(es) of Sites Audited (Specify activities performed at each site)</td><td colspan="2"></td></tr>
<tr><td>Total no. of employees</td><td colspan="2"></td></tr>
<tr><td>Contact Number</td><td colspan="2"></td></tr>
<tr><td>Fax Number</td><td colspan="2">Please indicate NA if this field is not applicable.</td></tr>
<tr><td rowspan="3">Name(s) and address(es) of outsourced service provider(s) for
(i) Storage
(ii) Distribution
(iii) Secondary assembly
(iv) Installation
(v) Servicing
(Specify activities performed at each site)</td><td>Activity Outsourced</td><td>Name & Address of Outsourced Service Provider(s)</td></tr>
<tr><td>E.g. Storage
(Please only select the given activity/activities on the left column.)</td><td>Please insert outsourced service provider’s name and address.

GDPMDS / ISO13485 certified / NA*
*delete as appropriate
See Note (1)

Certification Body:</td></tr>
<tr><td colspan="2">Note:
(1) The scope of certification of the service provider should cover the outsourced activities of the auditee.</td></tr>
</table>

SECTION B : PREVIOUS AUDIT
Applied GDPMDS Standard: *HSA TS-01 (Rev 2.1), dated September 2012* *or SS620:2016*
Date(s) of last audit: (dd/mm/yyyy)
Type of audit: ☐ Initial ☐ Surveillance ☐ Re-certification ☐ Special / Ad-hoc: (*Please specify details)*
Certification Body:
Verification of CAPA relating to previous audit: *Please indicate "Not applicable" if there is no CAPA required in the previous audit.*

SECTION C : CURRENT AUDIT
Applied GDPMDS Standard: *HSA TS-01 (Rev 2.1), dated September 2012* *or SS620:2016*
Date(s) of audit: (dd/mm/yyyy)
Type of audit: ☐ Initial ☐ Surveillance ☐ Re-certification ☐ Special / Ad-hoc: (*Please specify details)*
Total Man-Days:
Audit Team Leader: Audit Team Members:
Company's attendees at Opening Meeting (Name & Designation): *(May attach attendance list)*
Company's attendees at Closing Meeting (Name & Designation): *(May attach attendance list)*

SECTION D : CURRENT SCOPE OF CERTIFICATION
Activities : ☐ Import ☐ Storage ☐ Distribution ☐ Installation ☐ Servicing ☐ Secondary Assembly Storage and Handling Conditions: ☐ There are no special storage and handling conditions ☐ There are special storage and handling conditions *Please state the temperature range(s) applicable to the cold chain management (only for temperatures 8 °C and below)*
There are new activities / categories added since the last audit. ☐ Y ☐ N If 'Y', please specify details:
If there are activities and sites not covered in this audit, please state the reasons for exclusion:
Categories of Medical Devices: *(Refer to Table 1)*

Table 1: Categories of Medical Devices and Corresponding Activities *(Please indicate in the boxes as appropriate)*

Categories of Medical Devices	**Import**	**Storage**	**Distribution**	**Installation**	**Servicing**	**Secondary Assembly**	**Cold Chain Management (≤ 8oC)**	**All**
Active Implantable Devices	☐	☐	☐	☐	☐	☐	☐	☐
Anaesthetic and Respiratory Devices	☐	☐	☐	☐	☐	☐	☐	☐
Dental Devices	☐	☐	☐	☐	☐	☐	☐	☐
Diagnostic and Therapeutic Radiation Devices	☐	☐	☐	☐	☐	☐	☐	☐
Electro Mechanical Medical Devices	☐	☐	☐	☐	☐	☐	☐	☐
Technical Aids for Disabled Persons / Assistive Products for Persons with Disability *(applicable only for SS620:2016)*	☐	☐	☐	☐	☐	☐	☐	☐
Non-Active Implantable Devices	☐	☐	☐	☐	☐	☐	☐	☐
Ophthalmic and Optical Devices	☐	☐	☐	☐	☐	☐	☐	☐
Reusable Instruments/ Reusable Devices *(applicable only for SS620:2016)*	☐	☐	☐	☐	☐	☐	☐	☐
Single-Use Devices	☐	☐	☐	☐	☐	☐	☐	☐
Hospital Hardware	☐	☐	☐	☐	☐	☐	☐	☐
In Vitro Diagnostic Devices	☐	☐	☐	☐	☐	☐	☐	☐
Medical Software *(applicable only for SS620:2016)*	☐	☐	☐	☐	☐	☐	☐	☐

PART II: AUDIT COMMENTARY *(for TS-01 R2.1)*

SECTION A: AUDIT TRAIL *(NOTE: All fields to be completed, non-applicable fields should be marked as NA with justification)*	
Quality Management System	
Resource Management	
Storage and Stock Handling	
Traceability	
Medical Device Complaints (including Adverse Events)	
Field Safety Corrective Actions	
Return of Medical Devices	
Disposal of Medical Devices	
Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices	
Internal Audits	
Management Review	
Outsourced Activities	*(On-site audit is necessary for outsourced service providers of storage and secondary assembly that are not GDPMDS or ISO13485 certified)*
Secondary Assembly	

PART II: AUDIT COMMENTARY *(for SS620:2016)*

SECTION A: AUDIT TRAIL *(NOTE: All fields to be completed, non-applicable fields should be marked as NA with justification)*	
Quality Management System	
Management Responsibility	
Resource Management	
Premises and Facilities	
Secondary Assembly	
Traceability	
Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices	
Complaint Handling	
Field Safety Corrective Action (FSCA)	
Internal Audit	
Outsourced Activities	*(On-site audit is necessary for outsourced service providers of storage and secondary assembly that are not GDPMDS or ISO13485 certified)*

SECTION B: AUDIT FINDINGS	
List of Major Non-Conformities	*Please indicate NA if there is no major non-conformity.*
List of Minor Non-Conformities	*Please indicate NA if there is no minor non-conformity.*
Observations for Improvement	*Please indicate NA if there is no observation.*
Please indicate the due date for auditee to respond to the non-conformities	*Please indicate NA if there is no non-conformity.*
Remarks *(where applicable)*	
The findings in this audit have been explained to and accepted by the auditee.	
Name & Signature of Audit Team Leader:	Name & Signature of Auditee:
	Date (dd/mm/yyyy):
Date (dd/mm/yyyy): Company stamp: *(Optional if this report is printed on the certification body's official letterhead)*	Company stamp:

Annex 2

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES (GDPMDS) CERTIFICATE CONTENT

Certification Body Logo

This is to certify that ABC Organization has complied with standard

HSA TS-01 (Rev X): YYYY or SS620

Good Distribution Practice for Medical Devices- Requirements

Business Address

Site Address(es)

1 If registered address is also an audit site, it should be printed here

2 Site AA (can be included in Appendix)

3 Site AAA (can be included in Appendix)

There are X pages of Appendices attached with this certificate

Certificate No, Version, Date of Issue, Date of Expiry

ACCREDITED CERTIFICATION BODY SAC Cert No: ZZZZ-YYYY-XX

Site Address : **Location where the GDPMDS related activities are performed only by the certified company (excluding outsourced activities)**

Certification Body Logo

Scope of Certification

#Activities Outsourced	Name and Address of Outsourced Service Provider(s)
1) Please indicate "Not applicable" if there is no out-sourcing. *2) Outsourced activities refer to storage, distribution & secondary assembly only.*	

Applicable Special Storage and Handling Conditions

Appendix Page 1

Certificate No, Version, Date of Issue, Date of Expiry