QUALIFICATION PROTOCOL

7165 Sterilization Evaluation for Alaris Pump Infusion Sets sterilization in STERIGENICS Gamma facility (SCS0119).

Protocol No.: 10000347356 Revision No.:00

Review and Approval

The combined protocol has been reviewed and approved by the following individuals. Our collective signatures acknowledge that the document is ready for implementation to satisfy the requirements to validate process sterilization at STERIGENICS, Fort Worth, TX - Gamma Facility for ISD infusion sets 2420-0007, 2420-0500, 2426-0007 and 2426-0500. We individually agree with the contents of this protocol. .

The significance of each respective signature is shown below.

Written by:

Role	Name	Title	Signature	Date
Author	Maribel Huerta	Quality Control Specialist, Sterilization Services	See SAP	See SAP

Significance: The information in this protocol was assembled from the input of the other functions in this facility and is accurately reflected within this document.

Reviewed and Approved by:

Roles	Name	Title	Signature	Date
Quality	Edgar Esquerra	Staff Quality Engineer II	See SAP	See SAP
Process Owner	Anh Vo	Manager Quality Assurance, Sterility Assurance	See SAP	See SAP

Record Number 0710-005-002-R, DIR 10000347173, Version 00 Release Date 17JAN19
DOCO Use Only (Approver's Matrix) 0204-004-019-S (Latest Version)
DOCO Use Only (Record Format) 0204-004-014-R, DIR 10000324742, Ver 00, Release Date 12JAN18

Technical Reviewer	Tyler Mitchell	Lead Quality Control Technician	See SAP	See SAP
Validation	Maria Chevreuil	Sustaining engineer, Product engineer	See SAP	See SAP
Regulatory Affairs	Paulina Davis	Sr. Regulatory Affairs Specialist	See SAP	See SAP

Significance: We have reviewed and agree with the contents of this protocol. We agree the contents of this protocol meet all applicable requirements.

BD – *MDS*

San Diego CA, USA

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1. OBJECTIVE

1.1. The objective of this Process Validation (PV) protocol is to evaluate the sterilization of ISD sets 2420-0007, 2420-0500, 2426-0007 and 2426-0500 at Sterigenics Fort Worth, TX Gamma irradiation facility.

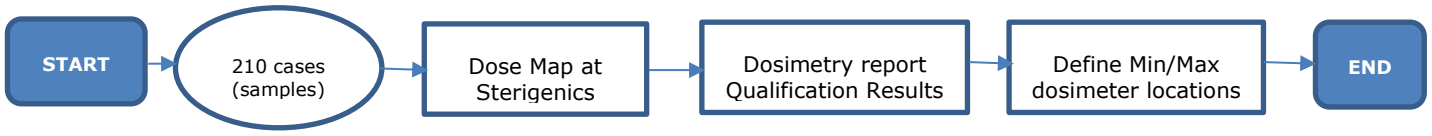
2. SCOPE

2.1 This protocol applies to models 2420-0007, 2420-0500, 2426-0007 and 2426-0500 currently manufactured in Tijuana and Nogales, Mexico and gamma sterilized at Steris Isomedix Services with a dose specification of 21.4-35.0kGy. The qualification of Sterigenics, Fort Worth, TX Gamma will serve as an additional sterilization facility/location for these models using the current dose range. There are no changes to packaging, production configuration, or manufacturing processes (See STR for 7165 STR STERIGENICS FORTWORTH TX, DIR 10000347265, 00).

2.1.1 Equipment to be validated:

Equipment Name and Description	Equipment Identification	Department and Site
Nordion JS-10000 Hanging tote irradiator	JS10000	Sterigenics / Fort Worth, TX

2.2 Process Description - Sample cases of a representative model from the ISD Alaris Sets will be subject to a dose map run at Sterigenics in order to determine the routine minimum and maximum dose locations for routine processing. The performance qualification will be performed per Sterigenics Gamma facility internal procedures.



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3. RESPONSIBILITIES:

3.1 The following table defines roles and responsibilities associated with this document.

Role	Responsibility
Author	• Prepare and submit the protocol for review and approval • Engage the plant and unit functions (as applicable) in creation of the validation plan and protocol. • Ensure that the plan and protocol meet technical and procedural requirements.
Quality	• Ensure that the validation plan and protocol are established in accordance with procedural requirements. • Ensure the content meets all applicable quality system requirements and product requirements.
Process Owner	• Ensure that the validation plan and protocol are established in accordance with procedural requirements. • Ensure the study design will evaluate the readiness of the process to be released to production.
Technical Reviewer	• Ensure that the validation plan and protocol are created in accordance with the equipment and process design • Ensure the strategy is appropriate and properly challenges the process technology.
Validation	• Ensure that plan and protocol meet requirements of the site validation master plan. • Ensure that the validation plan and protocol are established in accordance with procedural requirements.
Regulatory Affairs	• Ensure that plan and protocol meet regulatory requirements. • Ensure that the validation plan and protocol are established in accordance with procedural requirements.

4. VALIDATION STRATEGY

4.1 This study shall entail verification dose mapping using BD Alaris Infusion Sets to establish data (dosimeter placement) required for routine sterilization processing at Sterigenics Fort Worth, TX

Gamma facility. Physical dose mapping will be performed in accordance with Sterigenics standard operating procedures for dose mapping.

4.2 Per STERIGENICS loading requirements, densities from the models in the table below are considered homogenous and equivalent. Therefore, one (1) verification dose map for the qualification of models 2420-0007, 2420-0500, 2426-0007 and 2426-0500 will be conducted with 210 cases from model 2420-0007 as the models within the scope from this validation share same packaging requirements and have similar product configuration and density.

	Model	Shipper Dimensions (in)	Weight (lbs)	Density (gr/cm^3)
Gemini	2420-0007	$9\ ^{11/16} \times 7\ ^{5/8} \times 6\ ^{5/8}$	2.57	0.12
	2420-0500	$9\ ^{11/16} \times 7\ ^{5/8} \times 6\ ^{5/8}$	2.58	0.13
	2426-0007	$9\ ^{11/16} \times 7\ ^{5/8} \times 6\ ^{5/8}$	2.70	0.13
	2426-0500	$9\ ^{11/16} \times 7\ ^{5/8} \times 6\ ^{5/8}$	2.73	0.13

Table 1 Alaris Pump Infusion Sets.

4.3 Samples used for the dose map completion shall be built in accordance to New Sterilization Gamma site for Gemini Tj & Nogales (STERIGENICS, Fort Worth, TX Sample Build Test Protocol (DIR 10000347632, 00).

4.4 Dose mapping will be performed in accordance with STERIGENICS standard operating procedures, where the 210 sample cases will be loaded in 3 totes (70 cases per tote. See loading pattern in ATTACHMENT 1).

4.5 The dosimetry report from the dose mapping run shall be used for identifying and establishing the dosimeter routine locations placement.

4.6 After dose mapping a total of 15 cases (300 sets) must be returned to the BD Tijuana facility to complete the following functional tests:

4.6.1 Leak test.

4.6.2 Occlusion.

4.6.3 Retention test.

4.6.4 Retention test.

Note: Please review sample size justification within VP DIR 10000348795 section 5.1.2

4.7 No functional testing in product exposed to a radiation over 35.0 kGy is necessary as this was already performed as part form the IHC project. (See design Review 10000320802 DHF 6955; TP 10000303783, Build Protocol 10000307590, Build Report 10000312659 for further reference).

5. ACCEPTANCE CRITERIA

5.1 Dose map

5.1.1 The absorbed dose associated with each dosimeter placement position, the maximum and minimum dose locations shall be documented.

5.1.2 Dose mapping shall establish that the minimum dose delivered to the final product configurations is at least 21.4 kGy and the maximum dose delivered to the product does not exceed 35.0 kGy.

5.1.3 Conformance to ANSI/AAMI/ISO 11137-1:2013 'Requirements for development, validation and routine control of a sterilization process for medical devices'**.**

5.1.4 Conformance to ANSI/AAMI/ISO 11137-2:2013 'Establishing the sterilization dose**.**

5.2 Product functional testing

5.2.1 Functional testing is being performed to detect if there are differences within the processing practices that might adversely impact the functionality of our devices. Testing is to be performed on randomly sampled products after processing.

5.2.2 When tested per the product leak procedure ATP-007 (DIR 10000004835, 30), no leaks shall be found in the unions.

5.2.3 When tested per the PCP inspection procedure (DIR 10000004898, 74), no occlusion shall be found.

5.2.4 When tested per the retention and joint strength inspection procedure (DIR 10000004833, 31) no bond falls shall be found.

5.2.5 PQ shall demonstrate that:

5.2.5.1 All dosimeters placed in the mapping run are retrieved from their stated positions following irradiation, and are able to be analyzed and dose values documented.

5.2.5.2 Product irradiated according to Sterigenics defined process parameters can successfully achieve a minimum dose delivered of 21.4 kGy but no greater than 35.0 kGy.

5.2.5.3 Dose mapping results shall be used to establish the minimum and maximum dosimeter locations placement for routine processing.

KPOV / CTQ	Specification	Product Requirement Limit	Sample point	Inspection / Test Procedure	Minimum Number of samples	Frequency	Acceptance Criteria
Dose Map	21.4 – 35.0 kGy (SCS0103)	Max dose delivered 35.0 kGy. Min dose delivered 21.4 kGy	Per Sterigenics Internal requirements	Per Sterigenics Internal requirements	210 Cases (3 full totes)	1 (Once)	Minimum dose delivered = ≥21.4 kGy Maximum dose delivered = ≤35.0kGy
Leak test*	No leaks in unions/ 10000004898 PCP0017	No leaks in unions.	Per 10000004898 PCP0017 (after samples have been sterilized)	Reference 10000004835, ATP-007 TP Product Leak	299 Sets	1 (Once per dose map)	No leaks in unions.
Occlusion *	No occlusions / 10000004898 PCP0017	No occlusions in set.	Per 10000004898 PCP0017 (after samples have been sterilized)	Reference 10000000802	299 Sets	1 (Once per dose map)	No occlusions in set.
Retention test*	No bond falls/ 10000004898 PCP0017	No bond falls.	Per 10000004898 PCP0017 (after samples have been sterilized), ATP-004 Section 9.6	Reference 10000004833	76 Sets	1 (Once per dose map)	No bond falls.

*Note: References and data pertaining/relating to functional requirements are provided and defined by engineering as applicable.

6. DEVIATION HANDLING

6.1.1 Deviations to this approved protocol will be addressed per Instructions 0710-003-000-SWI. All deviations, including corrective actions, will be documented using Deviation Handling Form 0710-005-004-R.

7. REFERENCES

Document No.	Revision	Document Title
ANSI/AAMI/ISO 11137-1:2013	Current revision	Sterilization of healthcare products - Radiation
ANSI/AAMI/ISO 11137-2:2013	Current revision	Sterilization of healthcare products - Radiation
10000054814	01	0710-006-001-R Sterilization Technical Review
10000054810	02	0710-003-000-SWI Radiation Sterilization Validation and Dose Audit
10000347172	00	0710-005-001-R Validation Plan
10000347173	00	0710-005-002-R Protocol Template
10000347174	00	0710-005-003-R Report Template
10000347175	00	0710-005-004-R Deviation Handling Form
10000348795	00	Sterilization Evaluation for Alaris Pump Infusion Sets in Sterigenics Gamma facility Validation Plan
CO 1114103	N/A	Gemini sterigenics new sterilization site
10000347186	00	7165 Sterigenics Gamma site CA (SCS0119)
10000347265	00	STR for 7165 STR STERIGENICS FORTWORTH TX
10000004835	30	Product leak procedure ATP-007
10000004833	31	RETENTION AND JOINT STRENGTH Acceptance test procedure ATP-004

8. PERFORMANCE QUALIFICATION

8.1 Prerequisite Steps

8.1.1 Training will not be required for the sterilization run since the dose map will be performed according to STERIGENICS, Fort Worth internal procedures.

8.1.2 Personnel performing the functional testing procedure will be trained in this protocol.

8.2 Equipment

Name of Equipment	SAP Number (if applicable)/ Serial Number	Manufacturer	Calibration Due Date
JS10000	N/A	Nordion	*Per STERIGENICS internal procedures.

8.3 Materials

Model	Lot	Description
2420-0007	18125219	Alaris™ Pump Infusion Set Back Check Valve 2 SmartSite™ Y-site

8.4 Define PQ runs

8.4.1 BD Tijuana logistics department will ship 210 cases from model 2420-0007 to STERIGENICS in Forth Wort, TX.

8.4.2 Once received, STERIGENICS personnel shall run one dose map using 3 full totes with 70 cases in each tote using the loading configuration established in the attachment #1.

8.4.3 Once the dose mapping activities are completed STERIGENICS must return 15 cases for functional testing purposes.

8.4.4 Functional testing will be performed by PCP personnel located in BD Tijuana.

8.5 Collection of data

8.5.1 Dose map results report will be generated by STERIGENICS and shared with BD sterilization services department for final review.

8.5.2 Post-sterile functional testing will be recorded in attachment#2 (Post-sterile test forms).

8.5.3 Final qualification report shall be generated using document 0710-005-003-R Report Template (DIR 10000347174).

8.6 Review of data

8.6.1 STERIGENICS final certificate of processing must include the lot and model processed and clearly state the minimum and maximum dose delivered.

8.6.2 Final dosimetry report readings must be above or equal to 21.4 kGy and less or equal than 35.0 kGy.

8.7 Disposition of product

8.7.1 Product used for this qualification can be released if all acceptance criteria defined in section 5.0 is met.

8.7.2 The 15 cases (300 sets) destined for post-sterile functional testing are to be scrapped after this qualification is completed and prior to the lot final release.

8.8 Complete P.Q. report

8.8.1 At the conclusion of P.Q. activities, a report shall be created using Final Report Template 0710-005-003-R that will summarize the results and draw a conclusion on the validation.

8.8.2 Protocol report shall describe STERIGENICS internal controls for product handling.

8.8.3 If all required activities are successfully completed, SCS0119 (Sterilization Cycle Specification, 21.4 – 35.0 kGy) will be created for this location and added to the BOM structure of SKUs in section 4.2.

8.9 Qualification Appendices

8.9.1 Attachment#1 STERIGENICS loading configuration.

8.9.2 Attachment#2 Post-sterile test forms.

9. REVISION HISTORY

Revision Control Log			
REV. #	**Date**	**Change Description**	**Responsible**
1	See SAP	Initial Submission	Maribel Huerta