

## 510K Summary

### SteriTite Container System with MediTray Products

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**Trade Name** SteriTite Container System with MediTray Products

**Common Name** Sterilization Wrap Containers, Trays, Cassettes, and Other Accessories

**Class of Device** Class II

**Product Code** KCT

**Regulation** 21CFR880.6850

**Review Panel** General Hospital

**Establishment  
Registration Number** 2248608

**Predicate Device** K173259-SteriTite Rigid Container System with MediTrayProducts

**Description of Device** The SteriTite container system consists of a family of rigid reusable containers and inserts that provide an effective reusable sterilization packaging system for operating room instruments. The SteriTite container as previously cleared is available with solid or perforated base. The container is made of anodized aluminum with passivated stainless-steel hardware and silicone gaskets. Each filter retention plate with gaskets and off set vent pattern secures a disposable filter for bacterial barrier filtration. Filter retention plates in lid and base are interchangeable for universal use. A recessed gasket contributes to a knife edge fit between lid and base. Various instrument trays as well as stacked baskets and inserts including insert boxes, brackets, posts, partitions, and racks provide instrument protection and secure devices for sterilization within the container.

## Indications for Use

The SteriTite container and MediTray products are a reusable sterilization container system to be used to enclose other medical devices, which are to be sterilized, transported, and stored by a health care provider. It is intended to allow sterilization of the enclosed devices and maintain sterility of the enclosed device until it is used. This container system is compatible for use with the following low temperature sterilizers and cycles identified below:

- V-Pro 60 (Flexible and Lumen cycle).
- V-Pro s2 (Flexible and Lumen cycle).
- V-Pro maX 2 (Flexible and Lumen cycle)
- V-Pro maX (Flexible and Lumen cycle)
- STERRAD 100NX (ALLCLEAR-DUO Cycle)
- Sterizone VP4 (Cycle 1)

The SteriTite container with MediTray accessories has the following validated lumen claims in low temperature and pre-vacuum steam sterilization:

The following table (Table 1) identifies the lumen claims of the SteriTite container with MediTray parts in low temperature and steam sterilizers:

**Table 1. SteriTite Container System with MediTray Parts Lumen Claims**

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)	Validated Lumen Characteristics
STERIS V-Pro 60	Flexible	$\geq 1\text{mm} \times \leq 990\text{mm}$	Single or Dual Lumen
	Lumen	$\geq 0.77\text{mm} \times \leq 527\text{mm}$	Dual Channel
STERIS V-Pro s2	Flexible	$\geq 1\text{mm} \times \leq 990\text{mm}$	Single or Dual Lumen
	Lumen	$\geq 0.77\text{mm} \times \leq 527\text{mm}$	Dual Channel
STERIS V-Pro maX 2	Flexible	$\geq 1\text{mm} \times < 1050\text{mm}$	Single Lumen
STERIS V-Pro maX	Flexible	$\geq 1\text{mm} \times < 1050\text{mm}$	Single Lumen
	Lumen	$\geq 0.77\text{mm} \times \leq 527\text{mm}$	Dual Channel
STERRAD 100NX	DUO	$\geq 1\text{mm} \times \leq 875\text{mm}$	Single Lumen
Sterizone VP4	Cycle 1	$\geq 1.2\text{mm} \times \leq 1955\text{mm}$	Flexible Lumens
		$\geq 1.45\text{mm} \times \leq 3500\text{mm}$	Flexible Lumens
Steam	Pre-Vac	$\geq 2\text{mm} \times \leq 400\text{mm}$	Stainless Steel Lumen
		$\geq 1.2\text{mm} \times \leq 400\text{mm}$	Flexible Lumen

The following table (Table 2) displays the SteriTite part numbers and the sterilizers they are compatible with:

**Table 2. SteriTite Container Compatibility with Low Temperature and Steam Sterilizers**

V-Pro s2/60 Lumen Flex	V-Pro 1 Lumen	V-Pro maX/maX2 Lumen Flex	Sterizone VP4 Cycle 1	STERRAD 100NX DUO	STERRAD 100NX Standard Flex	STERRAD 100S/200 Standard	NX Advanced Standard	Steam Pre-vac Gravity IUSS
SC02MG	SC02MG	SC02MG	SC02M(G)*	SC02MG	SC02MG	SC02MG	SC02MG	SC02MG
SC03MG	SC03MG	SC03MG	SC03M(G)*	SC03MG	SC03MG	SC03MG	SC03MG	SC03MG
SC04MG	SC02NG	SC04MG	SC04M(G)*	SC04MG	SC04MG	SC04MG	SC04MG	SC04MG
SC02NG	SC03NG	SC02NG	SC02N(G)*	SC02NG	SC02NG	SC02NG	SC02NG	SC02NG
SC03NG	SC04FG	SC03NG	SC03N(G)*	SC03NG	SC03NG	SC03NG	SC03NG	SC03NG
SC04NLG	SC05FG	SC04NLG	SC04NL(G)*	SC04NLG	SC04NLG	SC04NLG	SC04HG	SC04NLG
SC05NLG	SC06FG	SC05NLG	SC05NL(G)*	SC05NLG	SC05NLG	SC05NLG	SC05HG	SC05NLG
SC04HG	SC08FG	SC04HG	SC04H(G)*	SC04HG	SC04HG	SC04HG	SC04QG	SC04HG
SC05HG	SC04HG	SC05HG	SC05H(G)*	SC05HG	SC05HG	SC05HG	SC05QG	SC05HG
SC04QG	SC05HG	SC06HG	SC06H(G)*	SC06HG	SC06HG	SC06HG	SC04FG	SC06HG
SC05QG	SC06HG	SC08HG	SC08H(G)*	SC08HG	SC08HG	SC08HG		SC08HG
SC04FG	SC08HG	SC04QG	SC04Q(G)*	SC04QG	SC04QG	SC04QG		SC04QG
	SC04QG	SC05QG	SC05Q(G)*	SC05QG	SC05QG	SC05QG		SC05QG
	SC05QG	SC06QG	SC06Q(G)*	SC04FG	SC06QG	SC06QG		SC06QG
	SC06QG	SC08QG	SC08Q(G)*	SC05FG	SC08QG	SC08QG		SC08QG
	SC08QG	SC04FG	SC04F(G)*	SC04LG	SC04FG	SC04FG		SC04FG
	SC04LG	SC05FG	SC04L(G)*	SC05WG	SC05FG	SC05FG		SC05FG
	SC06LG	SC06FG	SC06L(G)*		SC06FG	SC06FG		SC06FG
	SC08LG	SC08FG	SC08L(G)*		SC08FG	SC08FG		SC08FG
	SC05WG	SC04LG			SC04LG			SC04LG
		SC06LG			SC06LG			SC06LG
		SC08LG			SC08LG			SC08LG
		SC05WG			SC05WG			SC05WG

\*Please note that the SteriTite perforated bottom and solid bottom containers are compatible with the Sterizone VP4 Sterilizer.

The following table identifies which MediTray products are compatible with low temperature sterilizers and steam sterilization:

**Table 3. MediTray Products Sterilizer Compatibility Table**

MediTray Product	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S/200	STERRAD NX	STERIZONE VP4	Steam
<b>Baskets</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Trays</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Insert Boxes</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Metal Brackets</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Metal Partitions</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Posts</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Silicone Brackets</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Racks</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>Stringers</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following table identifies which SteriTite accessories are compatible with low temperature sterilizers and steam sterilization:

**Table 4. SteriTite Accessories Sterilizer Compatibility Table**

SteriTite Accessories	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S	STERRAD NX	STERIZONE VP4	Steam
SCF02 Round filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCFM02 Rectangular filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCS01W Tamper Evident Seals	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O23 Load Card Large	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O24 Load Card Small	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following tables (5-11) identify the sterilizer maximum load weight recommendations with the SteriTite containers:

**Table 5. SteriTite Container in V-Pro s2 and V-Pro 60 Maximum Load Weight Recommendations Including Weight of Container**

Part Number	Total Load Weight in V-Pro s2/60 Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02MG	25lbs	11lbs
SC03MG	25lbs	11lbs
SC04MG	25lbs	11lbs
SC02NG	25lbs	11lbs
SC03NG	25lbs	11lbs
SC04NLG	25lbs	11lbs
SC05NLG	25lbs	11lbs
SC04HG	25lbs	11lbs
SC05HG	25lbs	11lbs
SC04QG	25lbs	11lbs
SC05QG	25lbs	11lbs
SC04FG	25lbs	11lbs

**Table 6. SteriTite Container in STERRAD NX Maximum Load Weight Recommendations Including Weight of Container**

Part Number	Total Load Weight in NX Standard Cycle	Total Load Weight in NX Advanced Cycle
SC02MG	10.7lbs	10.7lbs
SC03MG	10.7lbs	10.7lbs
SC04MG	10.7lbs	10.7lbs
SC02NG	10.7lbs	10.7lbs
SC03NG	10.7lbs	10.7lbs
SC04HG	10.7lbs	10.7lbs
SC05HG	10.7lbs	10.7lbs
SC04QG	10.7lbs	10.7lbs
SC05QG	10.7lbs	10.7lbs
SC04FG	10.7lbs	10.7lbs

**Table 7. SteriTite Container in V-Pro 1  
Maximum Load Weight Recommendations  
Including Weight of Container**

Part Number	Total Load Weight in V-Pro 1 Lumen Cycle
SC02MG	19.65lbs
SC03MG	19.65lbs
SC02NG	19.65lbs
SC03NG	19.65lbs
SC04FG	19.65lbs
SC05FG	19.65lbs
SC06FG	19.65lbs
SC08FG	19.65lbs
SC04HG	19.65lbs
SC05HG	19.65lbs
SC06HG	19.65lbs
SC08HG	19.65lbs
SC04QG	19.65lbs
SC05QG	19.65lbs
SC06QG	19.65lbs
SC08QG	19.65lbs
SC04LG	19.65lbs
SC06LG	19.65lbs
SC08LG	19.65lbs
SC05WG	19.65lbs

**Table 8. SteriTite Container in STERRAD 100s/200  
Maximum Load Weight Recommendations  
Including Weight of Container**

Part Number	Total Load Weight in the STERRAD 100s/200 Standard Cycle
SC02MG	22lbs
SC03MG	22lbs
SC04MG	22lbs
SC02NG	22lbs
SC03NG	22lbs
SC04NLG	22lbs
SC05NLG	22lbs
SC04HG	22lbs
SC05HG	22lbs
SC06HG	22lbs
SC08HG	22lbs
SC04QG	22lbs
SC05QG	22lbs
SC06QG	22lbs
SC08QG	22lbs
SC04FG	22lbs
SC05FG	22lbs
SC06FG	22lbs
SC08FG	22lbs

**Table 9. SteriTite Container in 100NX  
Maximum Load Weight Recommendations  
Including Weight of Container**

Part Number	Total Load Weight in 100NX Standard Cycle	Total Load Weight in 100NX Flex Cycle	Total Load Weight in 100NX DUO Cycle
SC02MG	21.4lbs	21.4lbs	13.2lbs
SC03MG	21.4lbs	21.4lbs	13.2lbs
SC04MG	21.4lbs	21.4lbs	13.2lbs
SC02NG	21.4lbs	21.4lbs	13.2lbs
SC03NG	21.4lbs	21.4lbs	13.2lbs
SC04NLG	21.4lbs	21.4lbs	13.2lbs
SC05NLG	21.4lbs	21.4lbs	13.2lbs
SC04HG	21.4lbs	21.4lbs	13.2lbs
SC05HG	21.4lbs	21.4lbs	13.2lbs
SC06HG	21.4lbs	21.4lbs	13.2lbs
SC08HG	21.4lbs	21.4lbs	13.2lbs
SC04QG	21.4lbs	21.4lbs	13.2lbs
SC05QG	21.4lbs	21.4lbs	13.2lbs
SC06QG	21.4lbs	21.4lbs	NA
SC08QG	21.4lbs	21.4lbs	NA
SC04FG	21.4lbs	21.4lbs	13.2lbs
SC05FG	21.4lbs	21.4lbs	13.2lbs
SC06FG	21.4lbs	21.4lbs	NA
SC08FG	21.4lbs	21.4lbs	NA
SC04LG	21.4lbs	21.4lbs	13.2lbs
SC06LG	21.4lbs	21.4lbs	NA
SC08LG	21.4lbs	21.4lbs	NA
SC05WG	21.4lbs	21.4lbs	13.2lbs

**Table 10. SteriTite Container in V-Pro maX/maX 2  
Maximum Load Weight Recommendations  
Including Weight of Container**

Part Number	Total Load Weight in V-Pro maX/maX2 Lumen Cycle	Total Load Weight in V-Pro maX/maX2 Flex Cycle	Total Load Weight in V-Pro maX/maX2 Non-Lumen Cycle
SC02MG	19.65lbs	24lbs	50lbs
SC03MG	19.65lbs	24lbs	50lbs
SC04MG	19.65lbs	24lbs	50lbs
SC02NG	19.65lbs	24lbs	50lbs
SC03NG	19.65lbs	24lbs	50lbs
SC04NLG	19.65lbs	24lbs	50lbs
SC05NLG	19.65lbs	24lbs	50lbs
SC04HG	19.65lbs	24lbs	50lbs
SC05HG	19.65lbs	24lbs	50lbs
SC06HG	19.65lbs	24lbs	50lbs
SC08HG	19.65lbs	24lbs	50lbs
SC04QG	19.65lbs	24lbs	50lbs
SC05QG	19.65lbs	24lbs	50lbs
SC06QG	19.65lbs	24lbs	50lbs
SC08QG	19.65lbs	24lbs	50lbs
SC04FG	19.65lbs	24lbs	50lbs
SC05FG	19.65lbs	24lbs	50lbs
SC06FG	19.65lbs	24lbs	50lbs
SC08FG	19.65lbs	24lbs	50lbs
SC04LG	19.65lbs	24lbs	50lbs
SC06LG	19.65lbs	24lbs	50lbs
SC08LG	19.65lbs	24lbs	50lbs
SC05WG	19.65lbs	24lbs	50lbs

**Table 11. SteriTite Container in Steam Sterilization/IUSS  
Maximum Load Weight Recommendations  
Including Weight of Container**

Part Number	Total Load Weight in Steam Sterilization Pre-Vacuum Cycle	Total Load Weight in Steam Sterilization Gravity Cycle
SC02MG	35lbs	35lbs
SC03MG	35lbs	35lbs
SC04MG	35lbs	35lbs
SC02NG	35lbs	35lbs
SC03NG	35lbs	35lbs
SC04NLG	35lbs	35lbs
SC05NLG	35lbs	35lbs
SC04HG	35lbs	35lbs
SC05HG	35lbs	35lbs
SC06HG	35lbs	35lbs
SC08HG	35lbs	35lbs
SC04QG	35lbs	35lbs
SC05QG	35lbs	35lbs
SC06QG	35lbs	35lbs
SC08QG	35lbs	35lbs
SC04FG	35lbs	35lbs
SC05FG	35lbs	35lbs
SC06FG	35lbs	35lbs
SC08FG	35lbs	35lbs
SC04LG	35lbs	35lbs
SC06LG	35lbs	35lbs
SC08LG	35lbs	35lbs
SC05WG	35lbs	35lbs

## Technological Characteristics Comparison

All functional and design characteristics are the same as the predicate previously cleared and show effective performance characteristics. The SteriTite container system is the same container system previously cleared and demonstrated the same technical and performance characteristics previously. Sterilization efficacy testing has been conducted to support new indications.

## Summary of Non-Clinical Performance Testing

Case Medical, Inc. follows the “overkill method” of sterility assurance to show an elimination of a biological challenge. All SteriTite containers were tested with inner baskets or trays representative of the MediTray line of products. Testing was designed to simulate worst-case scenarios with half cycles utilized with end of shelf-life concentrations of hydrogen peroxide for low temperature sterilization. The bacterial strain *G. stearothermophilus* was used in all testing due to its resistance to moist heat and hydrogen peroxide. The validation testing was conducted at qualified independent laboratories in accordance with FDA guidance and available ANSI/AAMI standards such as ANSI/AAMI ST77, AAMI TIR 12 and ANSI/AMMI ST79.

Based on the testing performed on the SteriTite container and MediTray parts, the device has demonstrated compatibility with the sterilizers indicated above. Results are summarized in Table 12.

**Table 12: Summary of Non-Clinical Performance Testing**

Performance Testing	Standard	Purpose	Results
Sterility Maintenance	ANSI/AAMI ST77:2013 (R)2018	Demonstrate the integrity of the container to maintain sterility of contents over time and with multiple handling events after sterilization	Pass
Whole Package Microbial Challenge	ANSI/AAMI ST77:2013 (R)2018	Demonstration of whole package integrity following exposure to aerosolized bacterial spores.	Pass
Biocompatibility	ANSI AAMI ISO 10993-1	Acute systemic toxicity, primary irritation and sensitization of the subject device.	Pass
Material Compatibility / Re-Use Testing	ANSI/AAMI ST77:2013 (R)2018	Demonstration that the subject device materials are compatible with the intended sterilization cycles	Pass
Simulated Use Testing / Sterilization Efficacy	ANSI AAMI ISO 14937:2009/(R)2013	Testing was completed to demonstrate sterilization efficacy of the subject device for processing of medical devices with the indicated claims using the identified sterilization processes.	Pass

## Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K212711, the SteriTite Universal Container System and MediTray Products, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K173259.