March 22, 2024

Bahadir USA LLC
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K233578
Trade/Device Name: Bahadir Sterilization Containers
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 21, 2024
Received: February 21, 2024

Dear Joseph Azary:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.03.22 11:03:05 -04'00'

for Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233578

Device Name
Bahadir Sterilization Containers

Indications for Use *(Describe)*

Bahadir Sterilization Containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during low temperature hydrogen peroxide sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. This container system is compatible for use with the following low temperature sterilizers and the cycles identified below:

*STERIS V-PRO maX/maX2 - Lumen, Non-Lumen and Flexible Cycles
*STERIS V-PRO s2/60 - Lumen, Non-Lumen and Flexible Cycles
*STERRAD 100NX - Duo, Express, Standard and Flex Cycles
*STERRAD NX - Standard and Advanced Cycles

Bahadir Sterilization Containers Lumen Configurations

Sterilization Cycle	Container Size	Compatible Lumens
STERIS VPRO maX/maX2 Lumen Cycle	Full Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) ≥4mm x ≤424mm (rigid non-metallic lumen)
	Three-Quarter Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) ≥4mm x ≤424mm (rigid non-metallic lumen)
	Half Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen)

		≥4mm x ≤424mm (rigid non-metallic lumen)
STERIS VPRO maX/maX2 Flexible Cycle	Full Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
	Three-Quarter Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
	Half Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
STERIS VPRO maX/maX2 Non-Lumen Cycle	Full Size	-Non lumened instruments
	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
	Full Size	≥0.77mm x ≤410mm (single or dual channel)

STERIS VPRO s2/60 Lumen cycle		≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
	Three-Quarter Size	≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
	Half Size	≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
STERIS VPRO s2/60 Flexible Cycle	Full Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
	Three-Quarter Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
	Half Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
STERIS VPRO s2/60 Non-Lumen Cycle	Full Size	-Non lumened instruments
	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
STERRAD NX	Full Size	(5) SS lumens 1mm I.D. x 150mm L (5) SS lumens 2mm I.D. x 400mm L

Standard Cycle	Three-Quarter Size	(10) SS lumens 1mm I.D. x 150mm L
	Half Size	(10) SS lumens 1mm I.D. x 150mm L
STERRAD NX Advanced Cycle	Full Size	(10) SS lumens 2mm I.D. x 500mm L
	Three-Quarter Size	(6) SS lumens 1mm I.D. x 350mm L
	Half Size	(10) SS lumens 1mm I.D. x 200mm L
STERRAD 100NX Standard Cycle	Full Size	(5) SS lumens 1mm I.D. x 500mm L
	Three-Quarter Size	(5) SS lumens 1mm I.D. x 350mm L
	Half Size	(5) SS lumens 0.7mm I.D. x 200mm L
STERRAD 100NX Express Cycle	Full Size	Non lumened SS instruments
	Three-Quarter Size	Non lumened SS instruments
	Half Size	Non lumened SS instruments
STERRAD 100NX Duo Cycle	Full Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
	Three-Quarter Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
STERRAD 100 NX Flexible Cycle	Full Size	(1) Scope lumen 1mm I.D. x 850mm L
	Three-Quarter Size	(1) Scope lumen 1mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1mm I.D. x 850mm L

Bahadir Sterilization Containers Configurations

Sterilization Cycle	Container Size	Container Name	Total Loaded Container (lbs)
STERIS VPRO maX/maX2 Lumen Cycle	Full Size 4 ⅛”	Y111.10	19.65
	Full Size 5 ¼”	Y111.13	19.65
	Full Size 5 ⅞”	Y111.15	19.65
	Full Size 7 ¾”	Y111.20	19.65
	Full Size 10 ¼ “	Y111.26	19.65
	Full Size 7 ¾”	Y111.70	19.65
	Three-Quarter Size 4 ⅛”	Y211.10	19.65
	Three-Quarter Size 5 ¼”	Y211.13	19.65
	Three-Quarter Size 5 ⅞”	Y211.15	19.65
	Three-Quarter Size 7 ¾”	Y211.20	19.65
	Half Size 4 ⅛”	Y311.10	15
	Half Size 5 ¼”	Y311.13	15
	Half Size 5 ⅞”	Y311.15	15
	Half Size 7 ¾”	Y311.20	15
	Half Size 10 ¼”	Y311.26	15
	Full Size 4 ⅛”	Y111.10	21
	Full Size 5 ¼”	Y111.13	21
	Full Size 5 ⅞”	Y111.15	21
	Full Size 7 ¾”	Y111.20	21
	Full Size 10 ¼ “	Y111.26	21
	Full Size 7 ¾”	Y111.70	21

STERIS VPRO maX/maX2 Flexible Cycle	Three-Quarter Size 4 ⅛”	Y211.10	21
	Three-Quarter Size 5 ¼”	Y211.13	21
	Three-Quarter Size 5 ⅞”	Y211.15	21
	Three-Quarter Size 7 ¾”	Y211.20	21
	Half Size 4 ⅛”	Y311.10	21
	Half Size 5 ¼”	Y311.13	21
	Half Size 5 ⅞”	Y311.15	21
	Half Size 7 ¾”	Y311.20	21
	Half Size 10 ¼”	Y311.26	21
STERIS VPRO maX/maX2 Non-Lumen Cycle	Full Size 4 ⅛”	Y111.10	26
	Full Size 5 ¼”	Y111.13	26
	Full Size 5 ⅞”	Y111.15	26
	Full Size 7 ¾”	Y111.20	26
	Full Size 10 ¼ “	Y111.26	26
	Full Size 7 ¾”	Y111.70	26
	Three-Quarter Size 4 ⅛”	Y211.10	26
	Three-Quarter Size 5 ¼”	Y211.13	26
	Three-Quarter Size 5 ⅞”	Y211.15	26
	Three-Quarter Size 7 ¾”	Y211.20	26
	Half Size 4 ⅛”	Y311.10	19
	Half Size 5 ¼”	Y311.13	19
	Half Size 5 ⅞”	Y311.15	19
	Half Size 7 ¾”	Y311.20	19
	Half Size 10 ¼”	Y311.26	19
STERIS VPRO S2/60 Lumen Cycle	Full Size 4 ⅛”	Y111.10	11
	Full Size 5 ¼”	Y111.13	11
	Full Size 5 ⅞”	Y111.15	11
	Full Size 7 ¾”	Y111.20	11
	Full Size 10 ¼ “	Y111.26	11
	Full Size 7 ¾”	Y111.70	11
	Three-Quarter Size 4 ⅛”	Y211.10	11
	Three-Quarter Size 5 ¼”	Y211.13	11
	Three-Quarter Size 5 ⅞”	Y211.15	11
	Three-Quarter Size 7 ¾”	Y211.20	11
	Half Size 4 ⅛”	Y311.10	11
	Half Size 5 ¼”	Y311.13	11
	Half Size 5 ⅞”	Y311.15	11
	Half Size 7 ¾”	Y311.20	11
	Half Size 10 ¼”	Y311.26	11
STERIS VPRO S2/60 Flexible Cycle	Full Size 4 ⅛”	Y111.10	11
	Full Size 5 ¼”	Y111.13	11
	Full Size 5 ⅞”	Y111.15	11
	Full Size 7 ¾”	Y111.20	11
	Full Size 10 ¼ “	Y111.26	11
	Full Size 7 ¾”	Y111.70	11
	Three-Quarter Size 4 ⅛”	Y211.10	11
	Three-Quarter Size 5 ¼”	Y211.13	11
	Three-Quarter Size 5 ⅞”	Y211.15	11
	Three-Quarter Size 7 ¾”	Y211.20	11
	Half Size 4 ⅛”	Y311.10	11
	Half Size 5 ¼”	Y311.13	11
	Half Size 5 ⅞”	Y311.15	11
	Half Size 7 ¾”	Y311.20	11
	Half Size 10 ¼”	Y311.26	11
	Full Size 4 ⅛”	Y111.10	19
	Full Size 5 ¼”	Y111.13	19

	Full Size 5 ⅞”	Y111.15	19
	Full Size 7 ¾”	Y111.20	19
	Full Size 10 ¼ “	Y111.26	19
	Full Size 7 ¾”	Y111.70	19
STERIS VPRO	Three-Quarter Size 4 ⅛”	Y211.10	19
S2/60	Three-Quarter Size 5 ¼”	Y211.13	19
Non-Lumen Cycle	Three-Quarter Size 5 ⅞”	Y211.15	19
	Three-Quarter Size 7 ¾”	Y211.20	19
	Half Size 4 ⅛”	Y311.10	12.5
	Half Size 5 ¼”	Y311.13	12.5
	Half Size 5 ⅞”	Y311.15	12.5
	Half Size 7 ¾”	Y311.20	12.5
	Half Size 10 ¼”	Y311.26	12.5
	Full Size 4 ⅛”	Y111.10	10.7
	Full Size 5 ¼”	Y111.13	10.7
	Full Size 5 ⅞”	Y111.15	10.7
	Full Size 7 ¾”	Y111.20	10.7
	Full Size 10 ¼ “	Y111.26	10.7
	Full Size 7 ¾”	Y111.70	10.7
STERRAD NX	Three-Quarter Size 4 ⅛”	Y211.10	10.7
	Three-Quarter Size 5 ¼”	Y211.13	10.7
Standard Cycle	Three-Quarter Size 5 ⅞”	Y211.15	10.7
	Three-Quarter Size 7 ¾”	Y211.20	10.7
	Half Size 4 ⅛”	Y311.10	10.7
	Half Size 5 ¼”	Y311.13	10.7
	Half Size 5 ⅞”	Y311.15	10.7
	Half Size 7 ¾”	Y311.20	10.7
	Half Size 10 ¼”	Y311.26	10.7
	Full Size 4 ⅛”	Y111.10	10.7
	Full Size 5 ¼”	Y111.13	10.7
	Full Size 5 ⅞”	Y111.15	10.7
	Full Size 7 ¾”	Y111.20	10.7
	Full Size 10 ¼ “	Y111.26	10.7
	Full Size 7 ¾”	Y111.70	10.7
STERRAD NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Advanced Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	10.7
	Half Size 5 ¼”	Y311.13	10.7
	Half Size 5 ⅞”	Y311.15	10.7
	Half Size 7 ¾”	Y311.20	10.7
	Half Size 10 ¼”	Y311.26	10.7
	Full Size 4 ⅛”	Y111.10	21.4
	Full Size 5 ¼”	Y111.13	21.4
	Full Size 5 ⅞”	Y111.15	21.4
	Full Size 7 ¾”	Y111.20	21.4
	Full Size 10 ¼ “	Y111.26	21.4
	Full Size 7 ¾”	Y111.70	21.4
STERRAD 100NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Standard Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85

	Half Size 7 ¾”	Y311.20	13.85
	Half Size 10 ¼”	Y311.26	13.85
	Full Size 4 ⅛”	Y111.10	21.4
	Full Size 5 ¼”	Y111.13	21.4
	Full Size 5 ⅞”	Y111.15	21.4
	Full Size 7 ¾”	Y111.20	21.4
	Full Size 10 ¼ “	Y111.26	21.4
	Full Size 7 ¾”	Y111.70	21.4
STERRAD 100NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Express Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85
	Half Size 7 ¾”	Y311.20	13.85
	Half Size 10 ¼”	Y311.26	13.85
	Full Size 4 ⅛”	Y111.10	13.2
	Full Size 5 ¼”	Y111.13	13.2
	Full Size 5 ⅞”	Y111.15	13.2
	Full Size 7 ¾”	Y111.20	13.2
	Full Size 10 ¼ “	Y111.26	13.2
	Full Size 7 ¾”	Y111.70	13.2
STERRAD 100NX	Three-Quarter Size 4 ⅛”	Y211.10	13.2
	Three-Quarter Size 5 ¼”	Y211.13	13.2
DUO Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.2
	Three-Quarter Size 7 ¾”	Y211.20	13.2
	Half Size 4 ⅛”	Y311.10	7.2
	Half Size 5 ¼”	Y311.13	7.2
	Half Size 5 ⅞”	Y311.15	7.2
	Half Size 7 ¾”	Y311.20	7.2
	Half Size 10 ¼”	Y311.26	7.2
	Full Size 4 ⅛”	Y111.10	12.59
	Full Size 5 ¼”	Y111.13	12.59
	Full Size 5 ⅞”	Y111.15	12.59
	Full Size 7 ¾”	Y111.20	12.59
	Full Size 10 ¼ “	Y111.26	12.59
	Full Size 7 ¾”	Y111.70	12.59
STERRAD 100NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Flexible Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85
	Half Size 7 ¾”	Y311.20	13.85
	Half Size 10 ¼”	Y311.26	13.85

Bahadir Sterilization Containers may be used with Bahadir USA accessories according to the table below:

Cycle	Baskets including holding pins, holding clamps, silicone holders, partition sheets, tamper evident locks	Silicone Mats
Steris VPRO 60/s2 Lumen, Non-Lumen, Flex	YES	YES
Steris VPRO maX/maX2 Lumen, Non-Lumen, Flex	YES	YES
STERRAD NX – Standard	YES	NO
STERRAD NX – Advanced	YES	NO
STERRAD 100NX – Standard	YES	NO
STERRAD 100NX – Duo	YES	NO
STERRAD 100NX – Flex	YES	NO
STERRAD 100NX - Express	YES	YES

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K233578

DATE PREPARED: March 16, 2024

COMPANY NAME: BAHADIR USA LLC
431 SOUTH PENNSVILLE AUBURN RD
CARNEYS POINT, NJ 08069

CONTACT: ISMAIL KILIC
EMAIL: INFO@BAHADIRUSA.COM
OFFICE: 856-517-3080
FAX: 856-517-3081

PRIMARY CORRESPONDANT/CONSULTANT

CONTACT: JOSEPH AZARY
AZTECH REGULATORY AND QUALITY LLC
EMAIL: JAZARY@RCN.COM
OFFICE: (203)242-6670

TRADE NAME: BAHADIR STERILIZATION CONTAINERS

COMMON NAME/ CLASSIFICATION NAME: STERILIZATION WRAP CONTAINERS, TRAYS, CASSETTES, AND OTHER ACCESSORIES

CLASS OF DEVICE: CLASS II

PRODUCT CODE: KCT

REGULATION: 21 CFR880.6850

REVIEW PANEL: GENERAL HOSPITAL

ESTABLISHMENT REGESTRATION NUMBER: 3005741909

PREDICATE DEVICE: K131407, Bahadir Sterilization Containers (Primary Predicate)

K214041, AESCULAP Aicon Container (Secondary Predicate)

DESCRIPTION OF DEVICE:

The Bahadir Sterilization Containers are a reusable container system intended for sterilization and storage of other medical devices. This container system is compatible for use with the following low temperature sterilizers and cycles identified below:

- STERIS VPRO maX/maX2: Lumen, Non Lumen, Flexible
- STERIS VPRO s2/60: Lumen, Non Lumen, Flexible
- STERRAD NX: Standard, Advanced
- STERRAD 100NX: Standard, Express, Flex, Duo

INDICATIONS FOR USE:

Bahadir Sterilization Containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during low temperature hydrogen peroxide sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. This container system is compatible for use with the following low temperature sterilizers and the cycles identified below:

*STERIS V-PRO maX/maX2 - Lumen, Non-Lumen and Flexible Cycles
*STERIS V-PRO s2/60 - Lumen, Non-Lumen and Flexible Cycles
*STERRAD 100NX - Duo, Express, Standard and Flex Cycles
*STERRAD NX - Standard and Advanced Cycles

Bahadir Sterilization Containers Lumen Configurations

Sterilization Cycle	Container Size	Compatible Lumens
STERIS VPRO maX/maX2 Lumen Cycle	Full Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) ≥4mm x ≤424mm (rigid non-metallic lumen)
	Three-Quarter Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) ≥4mm x ≤424mm (rigid non-metallic lumen)
	Half Size	≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel)

		≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) ≥4mm x ≤424mm (rigid non-metallic lumen)
STERIS VPRO maX/maX2 Flexible Cycle	Full Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
	Three-Quarter Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
	Half Size	(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light

		cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
STERIS VPRO maX/maX2 Non-Lumen Cycle	Full Size	-Non lumened instruments
	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
STERIS VPRO s2/60 Lumen cycle	Full Size	≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
	Three-Quarter Size	≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
	Half Size	≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
STERIS VPRO s2/60	Full Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be

Flexible Cycle		single or dual lumen device with lumens that are ≥1mm x ≤990mm
	Three-Quarter Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
	Half Size	-Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
STERIS VPRO s2/60 Non-Lumen Cycle	Full Size	-Non lumened instruments
	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
STERRAD NX Standard Cycle	Full Size	(5) SS lumens 1mm I.D. x 150mm L (5) SS lumens 2mm I.D. x 400mm L
	Three-Quarter Size	(10) SS lumens 1mm I.D. x 150mm L
	Half Size	(10) SS lumens 1mm I.D. x 150mm L
STERRAD NX Advanced Cycle	Full Size	(10) SS lumens 2mm I.D. x 500mm L
	Three-Quarter Size	(6) SS lumens 1mm I.D. x 350mm L
	Half Size	(10) SS lumens 1mm I.D. x 200mm L
STERRAD 100NX Standard Cycle	Full Size	(5) SS lumens 1mm I.D. x 500mm L
	Three-Quarter Size	(5) SS lumens 1mm I.D. x 350mm L
	Half Size	(5) SS lumens 0.7mm I.D. x 200mm L
STERRAD 100NX Express Cycle	Full Size	Non lumened SS instruments
	Three-Quarter Size	Non lumened SS instruments
	Half Size	Non lumened SS instruments

STERRAD 100NX Duo Cycle	Full Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
	Three-Quarter Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
STERRAD 100 NX Flexible Cycle	Full Size	(1) Scope lumen 1mm I.D. x 850mm L
	Three-Quarter Size	(1) Scope lumen 1mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1mm I.D. x 850mm L

Bahadir Sterilization Containers Configurations

Sterilization Cycle	Container Size	Container Name	Total Loaded Container (lbs)
STERIS VPRO maX/maX2 Lumen Cycle	Full Size 4 ⅛”	Y111.10	19.65
	Full Size 5 ¼”	Y111.13	19.65
	Full Size 5 ⅞”	Y111.15	19.65
	Full Size 7 ¾”	Y111.20	19.65
	Full Size 10 ¼ “	Y111.26	19.65
	Full Size 7 ¾”	Y111.70	19.65
	Three-Quarter Size 4 ⅛”	Y211.10	19.65
	Three-Quarter Size 5 ¼”	Y211.13	19.65
	Three-Quarter Size 5 ⅞”	Y211.15	19.65
	Three-Quarter Size 7 ¾”	Y211.20	19.65
	Half Size 4 ⅛”	Y311.10	15
	Half Size 5 ¼”	Y311.13	15
	Half Size 5 ⅞”	Y311.15	15
	Half Size 7 ¾”	Y311.20	15
	Half Size 10 ¼”	Y311.26	15
STERIS VPRO maX/maX2 Flexible Cycle	Full Size 4 ⅛”	Y111.10	21
	Full Size 5 ¼”	Y111.13	21
	Full Size 5 ⅞”	Y111.15	21
	Full Size 7 ¾”	Y111.20	21
	Full Size 10 ¼ “	Y111.26	21
	Full Size 7 ¾”	Y111.70	21
	Three-Quarter Size 4 ⅛”	Y211.10	21
	Three-Quarter Size 5 ¼”	Y211.13	21
	Three-Quarter Size 5 ⅞”	Y211.15	21
	Three-Quarter Size 7 ¾”	Y211.20	21
	Half Size 4 ⅛”	Y311.10	21
	Half Size 5 ¼”	Y311.13	21
	Half Size 5 ⅞”	Y311.15	21
	Half Size 7 ¾”	Y311.20	21
	Half Size 10 ¼”	Y311.26	21
	Full Size 4 ⅛”	Y111.10	26
	Full Size 5 ¼”	Y111.13	26
	Full Size 5 ⅞”	Y111.15	26
	Full Size 7 ¾”	Y111.20	26

STERIS VPRO maX/maX2 Non-Lumen Cycle	Full Size 10 ¼ “	Y111.26	26
	Full Size 7 ¾”	Y111.70	26
	Three-Quarter Size 4 ⅛”	Y211.10	26
	Three-Quarter Size 5 ¼”	Y211.13	26
	Three-Quarter Size 5 ⅞”	Y211.15	26
	Three-Quarter Size 7 ¾”	Y211.20	26
	Half Size 4 ⅛”	Y311.10	19
	Half Size 5 ¼”	Y311.13	19
	Half Size 5 ⅞”	Y311.15	19
	Half Size 7 ¾”	Y311.20	19
	Half Size 10 ¼”	Y311.26	19
STERIS VPRO S2/60 Lumen Cycle	Full Size 4 ⅛”	Y111.10	11
	Full Size 5 ¼”	Y111.13	11
	Full Size 5 ⅞”	Y111.15	11
	Full Size 7 ¾”	Y111.20	11
	Full Size 10 ¼ “	Y111.26	11
	Full Size 7 ¾”	Y111.70	11
	Three-Quarter Size 4 ⅛”	Y211.10	11
	Three-Quarter Size 5 ¼”	Y211.13	11
	Three-Quarter Size 5 ⅞”	Y211.15	11
	Three-Quarter Size 7 ¾”	Y211.20	11
	Half Size 4 ⅛”	Y311.10	11
	Half Size 5 ¼”	Y311.13	11
	Half Size 5 ⅞”	Y311.15	11
	Half Size 7 ¾”	Y311.20	11
	Half Size 10 ¼”	Y311.26	11
STERIS VPRO S2/60 Flexible Cycle	Full Size 4 ⅛”	Y111.10	11
	Full Size 5 ¼”	Y111.13	11
	Full Size 5 ⅞”	Y111.15	11
	Full Size 7 ¾”	Y111.20	11
	Full Size 10 ¼ “	Y111.26	11
	Full Size 7 ¾”	Y111.70	11
	Three-Quarter Size 4 ⅛”	Y211.10	11
	Three-Quarter Size 5 ¼”	Y211.13	11
	Three-Quarter Size 5 ⅞”	Y211.15	11
	Three-Quarter Size 7 ¾”	Y211.20	11
	Half Size 4 ⅛”	Y311.10	11
	Half Size 5 ¼”	Y311.13	11
	Half Size 5 ⅞”	Y311.15	11
	Half Size 7 ¾”	Y311.20	11
	Half Size 10 ¼”	Y311.26	11
STERIS VPRO S2/60 Non-Lumen	Full Size 4 ⅛”	Y111.10	19
	Full Size 5 ¼”	Y111.13	19
	Full Size 5 ⅞”	Y111.15	19
	Full Size 7 ¾”	Y111.20	19
	Full Size 10 ¼ “	Y111.26	19
	Full Size 7 ¾”	Y111.70	19
	Three-Quarter Size 4 ⅛”	Y211.10	19
	Three-Quarter Size 5 ¼”	Y211.13	19
	Three-Quarter Size 5 ⅞”	Y211.15	19

Cycle			
	Three-Quarter Size 7 ¾”	Y211.20	19
	Half Size 4 ⅛”	Y311.10	12.5
	Half Size 5 ¼”	Y311.13	12.5
	Half Size 5 ⅞”	Y311.15	12.5
	Half Size 7 ¾”	Y311.20	12.5
	Half Size 10 ¼”	Y311.26	12.5
	Full Size 4 ⅛”	Y111.10	10.7
	Full Size 5 ¼”	Y111.13	10.7
	Full Size 5 ⅞”	Y111.15	10.7
	Full Size 7 ¾”	Y111.20	10.7
	Full Size 10 ¼ “	Y111.26	10.7
	Full Size 7 ¾”	Y111.70	10.7
STERRAD NX	Three-Quarter Size 4 ⅛”	Y211.10	10.7
	Three-Quarter Size 5 ¼”	Y211.13	10.7
Standard Cycle	Three-Quarter Size 5 ⅞”	Y211.15	10.7
	Three-Quarter Size 7 ¾”	Y211.20	10.7
	Half Size 4 ⅛”	Y311.10	10.7
	Half Size 5 ¼”	Y311.13	10.7
	Half Size 5 ⅞”	Y311.15	10.7
	Half Size 7 ¾”	Y311.20	10.7
	Half Size 10 ¼”	Y311.26	10.7
	Full Size 4 ⅛”	Y111.10	10.7
	Full Size 5 ¼”	Y111.13	10.7
	Full Size 5 ⅞”	Y111.15	10.7
	Full Size 7 ¾”	Y111.20	10.7
	Full Size 10 ¼ “	Y111.26	10.7
	Full Size 7 ¾”	Y111.70	10.7
STERRAD NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Advanced Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	10.7
	Half Size 5 ¼”	Y311.13	10.7
	Half Size 5 ⅞”	Y311.15	10.7
	Half Size 7 ¾”	Y311.20	10.7
	Half Size 10 ¼”	Y311.26	10.7
	Full Size 4 ⅛”	Y111.10	21.4
	Full Size 5 ¼”	Y111.13	21.4
	Full Size 5 ⅞”	Y111.15	21.4
	Full Size 7 ¾”	Y111.20	21.4
	Full Size 10 ¼ “	Y111.26	21.4
	Full Size 7 ¾”	Y111.70	21.4
STERRAD 100NX	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
Standard Cycle	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85
	Half Size 7 ¾”	Y311.20	13.85

	Half Size 10 ¼”	Y311.26	13.85
STERRAD 100NX Express Cycle	Full Size 4 ⅛”	Y111.10	21.4
	Full Size 5 ¼”	Y111.13	21.4
	Full Size 5 ⅞”	Y111.15	21.4
	Full Size 7 ¾”	Y111.20	21.4
	Full Size 10 ¼ “	Y111.26	21.4
	Full Size 7 ¾”	Y111.70	21.4
	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85
	Half Size 7 ¾”	Y311.20	13.85
	Half Size 10 ¼”	Y311.26	13.85
STERRAD 100NX DUO Cycle	Full Size 4 ⅛”	Y111.10	13.2
	Full Size 5 ¼”	Y111.13	13.2
	Full Size 5 ⅞”	Y111.15	13.2
	Full Size 7 ¾”	Y111.20	13.2
	Full Size 10 ¼ “	Y111.26	13.2
	Full Size 7 ¾”	Y111.70	13.2
	Three-Quarter Size 4 ⅛”	Y211.10	13.2
	Three-Quarter Size 5 ¼”	Y211.13	13.2
	Three-Quarter Size 5 ⅞”	Y211.15	13.2
	Three-Quarter Size 7 ¾”	Y211.20	13.2
	Half Size 4 ⅛”	Y311.10	7.2
	Half Size 5 ¼”	Y311.13	7.2
	Half Size 5 ⅞”	Y311.15	7.2
	Half Size 7 ¾”	Y311.20	7.2
	Half Size 10 ¼”	Y311.26	7.2
STERRAD 100NX Flexible Cycle	Full Size 4 ⅛”	Y111.10	12.59
	Full Size 5 ¼”	Y111.13	12.59
	Full Size 5 ⅞”	Y111.15	12.59
	Full Size 7 ¾”	Y111.20	12.59
	Full Size 10 ¼ “	Y111.26	12.59
	Full Size 7 ¾”	Y111.70	12.59
	Three-Quarter Size 4 ⅛”	Y211.10	13.85
	Three-Quarter Size 5 ¼”	Y211.13	13.85
	Three-Quarter Size 5 ⅞”	Y211.15	13.85
	Three-Quarter Size 7 ¾”	Y211.20	13.85
	Half Size 4 ⅛”	Y311.10	13.85
	Half Size 5 ¼”	Y311.13	13.85
	Half Size 5 ⅞”	Y311.15	13.85
	Half Size 7 ¾”	Y311.20	13.85
	Half Size 10 ¼”	Y311.26	13.85

Bahadir Sterilization Containers may be used with Bahadir accessories according to the table below:

Cycle	Baskets including holding pins, holding clamps, silicone holders, partition sheets, tamper evident locks	Silicone Mats
Steris VPRO 60/s2 Lumen, Non-Lumen, Flex	YES	YES
Steris VPRO maX/maX2 Lumen, Non-Lumen, Flex	YES	YES
STERRAD NX – Standard	YES	NO
STERRAD NX – Advanced	YES	NO
STERRAD 100NX – Standard	YES	NO
STERRAD 100NX – Duo	YES	NO
STERRAD 100NX – Flex	YES	NO
STERRAD 100NX - Express	YES	YES

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The table below provides a summary of the device technological characteristics comparing the subject device and the predicate device(s). The subject device is offered in similar sizes and is comprised of similar materials of construction with the same principals of operation as the predicate devices.

Characteristic	Subject Device: Bahadir Sterilization Containers Product Code:KCT	Primary Predicate Device: Bahadir Sterilization Containers (K131407) Product Code:KCT	Reference Predicate Device: AESCULAP Aicon Container (K214041) Product Code: KCT	Comparison
Intended Use	Container to store devices during sterilization	Container to store devices during sterilization	Container to store devices during sterilization	SAME
Indications for Use	A device intended to be used to enclosed another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	A device intended to be used to enclosed another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	A device intended to be used to enclosed another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	SAME
Sterilization Modalities	-STERIS VPRO maX/maX2: Lumen, Non-Lumen, Flexible -STERIS VPRO 60/s2: Lumen, Non-Lumen, Flexible -STERRAD NX: standard, advanced -STERRAD 100NX:	-Prevac Steam	-Prevac Steam -STERIS VPRO maX/maX2: Lumen, Non-Lumen, Flexible -STERIS VPRO 60 Lumen, Non-Lumen, Flexible -STERRAD NX:	SIMILAR The primary predicate is cleared for Prevac Steam versus the subject device and reference

	Standard, DUO, Express, Flexible		standard, advanced -STERRAD 100NX: Standard, DUO, Express, Flexible -Ethylene Oxide -STERRAD 100S -STERIZONE VP4	predicate are cleared for Steris and Sterrad modalities.
Material	Container:Anodized Aluminum Gasket:Silicone	Container:Anodized Aluminum Gasket:SIlicone	Container:Anodized Aluminum Gasket:SIlicone	SAME
Filter type and material	Single use (polypropylene)	Single use (paper)	Single use (polypropylene)	SIMILAR The primary predicate uses paper filters whereas the subject device and reference predicate use polypropylene filters which are more appropriate for the low temperature hydrogen peroxide sterilization.
Container design	Perforated bottom with Perforated lid	Perforated or Non-Perforated bottom with Perforated Lid	Solid (non - perforated) bottom or Solid bottom with enhanced drying system with with Perforated Lid	SIMILAR Testing indicates that subject device performs equivalent to secondary predicate
Air Permeance	Permits entry of sterilization agent and prevents microbial migration during storage	Permits entry of sterilization agent and prevents microbial migration during storage	Permits entry of sterilization agent and prevents microbial migration during storage	SAME
Intended for Reuse	Yes	Yes	Yes	SAME
Conformance to AAMI ST77	Yes	Yes	Yes	SAME
Use with Cannulized Instruments	Yes	Yes	Yes	SAME

The Bahadir Sterilization Containers has the same intended use and principles of operation as the previously cleared predicate devices. The Bahadir Sterilization Containers is the same container system previously cleared in K131407 and demonstrated the same technical and performance characteristics. All functional and design characteristics of the subject device are the same as the primary predicate K131407, and similar to the reference predicate K214041.

The primary difference is that the subject device and reference predicate device both use low temperature hydrogen peroxide sterilization and use polypropylene filters, whereas the primary predicate device uses steam sterilization and paper filters.

Sterilization efficacy testing has been conducted to support the performance of the device when using the low temperature hydrogen peroxide sterilization cycles included in the new indications.

PERFORMANCE TESTING

Based on the testing performed on the Bahadir Sterilization Containers, compatibility has been demonstrated with the sterilizers indicated above. Results are summarized in the table below.

Test Method	Purpose	Acceptance Criteria	Results
Microbial Aerosol Challenge Testing Testing per standards AAMI ST77:2013/ (R)2018 AAMI ISO 11607-1:2019 AAMI ISO 14937:2009/ (R)2013 Test to be conducted post Mechanical Cleaning and STERIS V-PRO Lumen Cycle using worst case, mid case and best case containers. Test to be conducted post Mechanical Cleaning and STERRAD 100NX Standard Sterilization Cycle using worst case, mid case and best case containers.	To determine the microbial barrier properties of the Bahadir Container Systems in maintaining sterility package integrity when subjected to a microbial aerosol challenge test following processing: In one hundred mechanical cleaning and STERIS V-PRO Lumen Cycle sterilization cycles. In one hundred (100) mechanical cleaning and STERRAD 100NX Standard Sterilization Cycles. Full Size (Mid Case) in a STERIS V-PRO Lumen Cycle sterilization cycle. 3/4 Size (Worst Case) in a STERIS V-PRO Lumen Cycle sterilization cycle. ¾ size (Worst Case) in a STERRAD 100NX Standard Sterilization Cycle. ½ size (Best Case) in a STERRAD 100NX Standard Sterilization Cycle. full size (Mid Case) in a STERRAD 100NX Standard Sterilization Cycle.	The container systems must maintain sterility of its contents following whole package microbial aerosol challenge after 100 cleaning cycles and sterilization cycles (STERIS V-PRO Lumen Cycle and STERRAD 100NX Standard). The worst case, mid case and best case containers must be tested.	PASS – The results conclude that the Bahadir Container System maintained sterility of its contents following a whole package microbial aerosol challenge following processing: In one hundred mechanical cleaning and STERIS V-PRO Lumen Cycle sterilization cycles. In one hundred (100) mechanical cleaning and STERRAD 100NX Standard Sterilization Cycles. Full Size (Mid Case) in a STERIS V-PRO Lumen Cycle sterilization cycle. 3/4 Size (Worst Case) in a STERIS V-PRO Lumen Cycle sterilization cycle. ¾ size (Worst Case) in a STERRAD 100NX Standard Sterilization Cycle. ½ size (Best Case) in a STERRAD 100NX Standard Sterilization Cycle. full size (Mid Case) in a STERRAD 100NX Standard Sterilization Cycle.

Sterilization Validation Testing per standards AAMI ST77:2013/ (R)2018 AAMI ST81:2004/ (R)2016 AAMI ISO 14937:2009/ (R)2013Cycle. Test containers in the STERIS V-PRO 60/s2 Flexible Cycle. Test containers in the STERIS V-PRO maX / maX 2 lumen cycle and STERIS V-PRO 60/s2 lumen cycle. Test containers for STERRAD 100NX DUO, STERRAD NX Advanced, 100NX Standard, and 100NX Flex Cycle.	To validate the sterilization efficacy of the Bahadir Container Systems ¾ Size (Worst Case) Full Size (Mid Case) ½ Size (Best Case) when processed using: - STERRAD 100NX DUO Sterilization Cycle - STERRAD 100NX Flex Cycle - STERRAD NX Advanced Sterilization Cycle - STERRAD 100 NX Express Cycle - STERRAD 100NX Standard Cycle - STERRAD NX Standard Cycle	The container system must achieve an SAL of 10^{-6} when processed using the different sterilization modalities (STERIS V-PRO 60/s2, STERIS V-PRO maX/maX2 lumen cycle and STERRAD 100NX DUO, STERRAD NX Advanced, 100NX Standard, and 100NX Flex Cycles. Testing also must demonstrated sterilization efficacy with lumened devices and max loads.	PASS – Results from testing have demonstrated that the Bahadir Container Systems was able to achieve a 10^{-6} SAL when processed in: ¾ Size (Worst Case), ½ Size (Best Case) and Full (Mid Case) when processed in a STERRAD 100NX DUO Sterilization Cycle. ¾ (Worst Case), Full (Mid Case) after processing STERRAD NX Advanced Cycle. 3/4 Size (Worst Case), ½ Size (Best Case) and Full Size (Mid Case) after processing STERRAD 100NX FLEX Sterilization Cycle. ¾ Size (Worst Case), ½ Size (Best Case) and Full Size (Mid Case) after processing STERRAD 100NX Express Sterilization Cycle. ¾ Size (Worst Case), ½ Size (Best Case) and Full Size (Mid Case) after processing STERRAD 100NX Standard Sterilization Cycle. ¾ Size (Worst Case), ½ Size (Best Case) and Full Size (Mid Case) after processing STERRAD NX Standard Sterilization Cycle.

Sterilization Validation (continued)	The testing was to demonstrate effective sterilization using Bahadir Sterilization Containers in: - The STERIS V-PRO 60/s2 Flexible Cycle. The test load was prepared using a ¾ size (Worst Case). - The STERIS V-PRO maX / maX 2 Flexible Cycle. The test load was prepared using a ¾ size (Worst Case). - The STERIS V-PRO maX/maX2 and 60/s2 Non Lumen Cycle - The STERIS V-PRO maX/maX2 and 60/s2 Lumen Cycle	Continued	PASS – Effective sterilization using Bahadir Sterilization Containers was demonstrated after processing in the STERIS V-PRO 60/s2 Flexible Cycle with max load allowed ss lumens. Testing was performed with the worst-case container size and verified the claims for sterilizing: One flexible surgical endoscope may be single or dual lumen device with lumen that are ≥ 1mm ID and ≤ 990mm in length. Additional load up to 11 lb can include stainless steel lumens with following dimensions ≥ 1.8mm ID and ≤ 543mm in length, ≥ 0.76mm ID and ≤ 233 mm in length and ≥ 1.0mm ID and ≤ 254mm in length. And in the STERIS V-PRO maX/maX2 and 60/s2 non lumen cycle in a load using worst case sterilant penetration conditions in the V-PRO maX non lumen cycle. The testing verified that V-PRO maX/maX 2 non lumen cycle can sterilize non-lumened instruments and non-lumened rigid, semi-rigid and flexible endoscopes. And in the STERIS V-PRO maX/maX2 and 60/s2 Lumen Cycle in a load using worst case sterilant penetration conditions in the V-PRO maX/maX 2 lumen cycle can sterilize lumened device of different dimensions as outlined in the report.

Sterilization validation (continued)	(continued)	(continued)	And in the STERIS V-PRO maX / maX 2 Flexible Cycle in a load containing the maximum allowed ss lumens. Testing was performed with the worst case container and verified the claims for sterilizing: Two flexible endoscopes with no additional load. The flexible endoscopes may be single or dual lumen device with lumen that are ≥ 1mm ID and ≤ 1050mm in length. One flexible endoscope with accessories and additional instruments. The flexible endoscope may contain single or dual channel lumens that are ≥ 1mm ID and ≤ 1050mm in length. Additional instruments may include non-lumened or lumened medical devices with lumen that is ≥ 0.48mm ID and ≤ 100mm in length.
Material Compatibility of the Bahadir Containers to be assessed after Automated Cleaning and sterilization modalities (STERRAD 100NX Sterilization and STERIS V-PRO Sterilization).	To verify the material compatibility of the Bahadir Container Systems following automated cleaning and STERRAD 100NX Sterilization and STERIS V-PRO Sterilization	The containers must show no signs of degradation after automated cleaning and using different sterilization modalities (STERRAD 100NX and STERIS V-PRO)	PASS: No degradation was observed.

30 Day Event Related Shelf Life Study Test performed per standards: AAMI ST77:2013/ (R)2018 ISO 11607-1:2006/A1:2014/ (R)2019. ISO 14937:2009/ (R)2013 The testing is to include Worst case, mid case and best case for Bahadir containers following STERRAD 100NX Standard and STERIS V-PRO Lumen Cycles.	To demonstrate that the Bahadir Container Systems - ½ Size (Best Case) - ¾ Size (Worst Case) - Full Size (Mid Case) can effectively maintain the sterility of its internal contents following exposure to a - STERRAD 100NX Standard Sterilization cycle - STERIS V-PRO lumen cycle and a minimum 30-day event related storage period.	The containers must maintain sterility of internal components for a minimum of 30 days following exposure to STERRAD 100NX Standard cycle and STERIS V-PRO lumen cycle.	PASS: Based on the results of the testing the Bahadir Container Systems - ½ Size (Best Case) - ¾ Size (Worst Case) - Full Size (Mid Case) maintained the sterility of their contents following exposure to a - STERRAD 100NX Standard Sterilization Cycle - STERIS V-PRO lumen cycle For a minimum of a thirty (30) day shelf life storage period.
180 Day Event Related Shelf Life Study Testing performed per standards: AAMI ST77:2013/ (R)2018 ISO 11607-1:2006/A1:2014/ (R)2019. ISO 14937:2009/ (R)2013 Testing to include best case, worst case and mid case of the Bahadir Containers for different sterilization modalities (STERIS V-PRO Lumen cycle, STERRAD 100NX Standard cycle)	To demonstrate that the Bahadir Container Systems - ½ Size (Best Case) - ¾ Size (Worst Case) - Full Size (Mid Case) can effectively maintain the sterility of its internal contents following exposure to a - STERIS V-PRO lumen cycle - STERRAD 100NX Standard cycle and a minimum 180-day event related storage period.	The containers must maintain sterility of their contents for a minimum of 180 days following STERIS V-PRO lumen cycle and STERRAD 100NX Standard cycle).	PASS: Based on the results of the testing the Bahadir Container Systems - ½ Size (Best Case) - ¾ Size (Worst Case) - Full Size (Mid Case) maintained the sterility of their contents following exposure to a - STERIS V-PRO lumen cycle - STERRAD 100NX Standard Sterilization Cycle and a minimum 180 day shelf life storage period.

Cytotoxicity Testing Testing conducted per standard ISO 10993-5	To verify that the materials used for the Bahadir Sterilization Containers are non-cytotoxic. The testing included: - ½ size (Best Case) ISO Elution Method following STERIS V-PRO Sterilization - ½ size (Best Case) MEM Elution Method following STERRAD 100NX Standard Cycle Sterilization	The container materials must be classified as non-toxic per ISO 10994-5 standard.	PASS – The device was determined not to be cytotoxic. No cytotoxicity or cell lysis was noted.

SAFETY AND EFFICACY

The subject device has been tested to and complies with applicable consensus standards and FDA Guidance. All of the testing passed and there were no identified issues that would impact the safety, performance or efficacy of the subject device.

CONCLUSION

The conclusion drawn from the non-clinical testing demonstrates that the subject device, BAHADIR Sterilization Containers, submitted under K233578, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K131407.