



March 14, 2022

Care Essentials Pty Ltd
Abhay Sinha
Managing Director
103 Mornington Street
North Geelong, Victoria 3215
Australia

Re: K213907
Trade/Device Name: CareGUARD* Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 7, 2021
Received: December 14, 2021

Dear Abhay Sinha:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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

510(k) Number (if known)

K213907

Device Name

CareGUARD* Sterilization Wrap

Indications for Use (Describe)

CareGUARD* Sterilization Wrap is a single-use, non-woven sterilization wrap intended to be sterilized by a health care provider using pre-vacuum steam at 273°F / 134°C for 4 minutes. The CareGUARD* Sterilization Wrap was validated for a dry time of 30 minutes. The CareGUARD* Sterilization wrap is recommended to be used with trays weighing up to 13.7 lbs.

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

Test results validated that CareGUARD* Sterilization wraps allowed sterilization of the enclosed devices by pre-vacuum cycles.

Refer to Table 1 for recommendations for use per Pre-vacuum steam Sterility Maintenance Study.

Table 1: Basis weight recommendations for pre-vacuum steam

Basis Weight	Maximum Wrapped Package Content Weight
50 GSM	6.2 kg / 13.7 lbs
60 GSM	
75 GSM	

The following load was used in the Pre-vacuum steam Sterility Maintenance Study:

- 50 GSM: 21 in. x 10 in. x 4 ¾ in. (54 cm x 25 cm x 12 cm) tray containing 13.7 lbs (6.2 kg) of metal mass
The metal mass included surgical instruments used for orthopedic joint replacement

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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K213907

CareGUARD* Sterilization Wrap

510(k) SUMMARY

510(k) Applicant: Abhay Sinha
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Phone: +61-3-5277-1455
Email: queries@careessentials.com.au

510(k) Correspondent: Abhay Sinha
Care Essentials Pty. Ltd.
103 Mornington Street
North Geelong
Victoria, Australia 3215
Phone: +61-3-5277-1455
Email: queries@careessentials.com.au

Date of Summary: December 7, 2021

Type of 510(k) Submission: Traditional

Device Trade or Proprietary Name: CareGUARD*™ Sterilization Wrap
Common name: Sterilization Wrap
Classification Name: Wrap, Sterilization
Product Code: FRG
Classification Panel: General Hospital
Regulatory Class: Class II
Regulation #: 21 CFR 880.6850

Predicate Device: Kimberly-Clark* Corporation KIMGUARD*
Sterilization Wrap – K082554

Device Description

CareGUARD* Sterilization Wrap is made from 100% polypropylene spunbond-meltblown-spunbond (SMS) non-woven fabric. The sterilization wrap is provided in three different material basis weights of three product offerings in various dimensions. CareGUARD* Single Layer Sterilization wrap is comprised of a single sheet or one layer of SMS fabric. CareGUARD* Dual Layers Sterilization Wrap and CareGUARD* Contrast Sterilization Wrap, are comprised of two single layer sheets of SMS fabric ultrasonically bonded along two opposing edges. The wrap design allows for use of the sequential or simultaneous double-wrapping technique per recommendations from ANSI/AAMI ST79:2017 and allows for a sterilized pack to be opened aseptically. All basis weights utilize the same material technology. This product is a single-use and a non-sterile medical device.

CareGUARD* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using pre-vacuum steam at 273°F/134°C for 4 minutes.

TABLE 1: DIMENSIONS, TYPES AND BASIS WEIGHTS

No.	Model	Product Description
1	SW606050-B	CareGUARD* Single Layer, 60cm X 60cm (24" X 24"), 50GSM, Blue
2	SW606060-B	CareGUARD* Single Layer, 60cm X 60cm (24" X 24"), 60GSM, Blue
3	SW606075-B	CareGUARD* Single Layer, 60cm X 60cm (24" X 24"), 75GSM, Blue
4	SW767650-B	CareGUARD* Single Layer, 76cm X 76cm (30" X 30"), 50GSM, Blue
5	SW767660-B	CareGUARD* Single Layer, 76cm X 76cm (30" X 30"), 60GSM, Blue
6	SW767675-B	CareGUARD* Single Layer, 76cm X 76cm (30" X 30"), 75GSM, Blue
7	SW919150-B	CareGUARD* Single Layer, 91cm X 91cm (36" X 36"), 50GSM, Blue
8	SW919160-B	CareGUARD* Single Layer, 91cm X 91cm (36" X 36"), 60GSM, Blue
9	SW919175-B	CareGUARD* Single Layer, 91cm X 91cm (36" X 36"), 75GSM, Blue
10	SW10010050-B	CareGUARD* Single Layer, 100cm X 100cm (40" X 40"), 50GSM, Blue
11	SW10010060-B	CareGUARD* Single Layer, 100cm X 100cm (40" X 40"), 60GSM, Blue
12	SW10010075-B	CareGUARD* Single Layer, 100cm X 100cm (40" X 40"), 75GSM, Blue
13	SW11611650-B	CareGUARD* Single Layer, 116cm X 116cm (45" X 45"), 50GSM, Blue
14	SW11611660-B	CareGUARD* Single Layer, 116cm X 116cm (45" X 45"), 60GSM, Blue
15	SW11611675-B	CareGUARD* Single Layer, 116cm X 116cm (45" X 45"), 75GSM, Blue
16	SW12012050-B	CareGUARD* Single Layer, 120cm X 120cm (48" X 48"), 50GSM, Blue
17	SW12012060-B	CareGUARD* Single Layer, 120cm X 120cm (48" X 48"), 60GSM, Blue
18	SW12012075-B	CareGUARD* Single Layer, 120cm X 120cm (48" X 48"), 75GSM, Blue
19	SW13713750-B	CareGUARD* Single Layer, 137cm X 137cm (54" X 54"), 50GSM, Blue

20	SW13713760-B	CareGUARD* Single Layer, 137cm X 137cm (54" X 54"), 60GSM, Blue
21	SW13713775-B	CareGUARD* Single Layer, 137cm X 137cm (54" X 54"), 75GSM, Blue
22	SW13718250-B	CareGUARD* Single Layer, 137cm X 182cm (54" X 72"), 50GSM, Blue
23	SW13718260-B	CareGUARD* Single Layer, 137cm X 182cm (54" X 72"), 60GSM, Blue
24	SW13718275-B	CareGUARD* Single Layer, 137cm X 182cm (54" X 72"), 75GSM, Blue
25	SW606050-B/B	CareGUARD* Dual Layers, 60cm X 60cm (24" X 24"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
26	SW606060-B/B	CareGUARD* Dual Layers, 60cm X 60cm (24" X 24"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
27	SW606075-B/B	CareGUARD* Dual Layers, 60cm X 60cm (24" X 24"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
28	SW767650-B/B	CareGUARD* Dual Layers, 76cm X 76cm (30" X 30"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
29	SW767660-B/B	CareGUARD* Dual Layers, 76cm X 76cm (30" X 30"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
30	SW767675-B/B	CareGUARD* Dual Layers, 76cm X 76cm (30" X 30"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
31	SW919150-B/B	CareGUARD* Dual Layers, 91cm X 91cm (36" X 36"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
32	SW919160-B/B	CareGUARD* Dual Layers, 91cm X 91cm (36" X 36"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
33	SW919175-B/B	CareGUARD* Dual Layers, 91cm X 91cm (36" X 36"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
34	SW10010050-B/B	CareGUARD* Dual Layers, 100cm X 100cm (40" X 40"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
35	SW10010060-B/B	CareGUARD* Dual Layers, 100cm X 100cm (40" X 40"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
36	SW10010075-B/B	CareGUARD* Dual Layers, 100cm X 100cm (40" X 40"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
37	SW11611650-B/B	CareGUARD* Dual Layers, 116cm X 116cm (45" X 45"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
38	SW11611660-B/B	CareGUARD* Dual Layers, 116cm X 116cm (45" X 45"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
39	SW11611675-B/B	CareGUARD* Dual Layers, 116cm X 116cm (45" X 45"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
40	SW12012050-B/B	CareGUARD* Dual Layers, 120cm X 120cm (48" X 48"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM

41	SW12012060-B/B	CareGUARD* Dual Layers, 120cm X 120cm (48" X 48"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
42	SW12012075-B/B	CareGUARD* Dual Layers, 120cm X 120cm (48" X 48"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
43	SW13713750-B/B	CareGUARD* Dual Layers, 137cm X 137cm (54" X 54"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
44	SW13713760-B/B	CareGUARD* Dual Layers, 137cm X 137cm (54" X 54"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
45	SW13713775-B/B	CareGUARD* Dual Layers, 137cm X 137cm (54" X 54"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
46	SW13718250-B/B	CareGUARD* Dual Layers, 137cm X 182cm (54" X 72"), 50GSM, Blue/Blue Bonded, Two Layers, Total GSM: 100 GSM
47	SW13718260-B/B	CareGUARD* Dual Layers, 137cm X 182cm (54" X 72"), 60GSM, Blue/Blue Bonded, Two Layers, Total GSM: 120 GSM
48	SW13718275-B/B	CareGUARD* Dual Layers, 137cm X 182cm (54" X 72"), 75GSM, Blue/Blue Bonded, Two Layers, Total GSM: 150 GSM
49	SW606050-B/W	CareGUARD* Contrast, 60cm X 60cm (24" X 24"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
50	SW606060-B/W	CareGUARD* Contrast, 60cm X 60cm (24" X 24"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
51	SW606075-B/W	CareGUARD* Contrast, 60cm X 60cm (24" X 24"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
52	SW767650-B/W	CareGUARD* Contrast, 76cm X 76cm (30" X 30"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
53	SW767660-B/W	CareGUARD* Contrast, 76cm X 76cm (30" X 30"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
54	SW767675-B/W	CareGUARD* Contrast, 76cm X 76cm (30" X 30"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
55	SW919150-B/W	CareGUARD* Contrast, 91cm X 91cm (36" X 36"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
56	SW919160-B/W	CareGUARD* Contrast, 91cm X 91cm (36" X 36"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
57	SW919175-B/W	CareGUARD* Contrast, 91cm X 91cm (36" X 36"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
58	SW10010050-B/W	CareGUARD* Contrast, 100cm X 100cm (40" X 40"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
59	SW10010060-B/W	CareGUARD* Contrast, 100cm X 100cm (40" X 40"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM

60	SW10010075-B/W	CareGUARD* Contrast, 100cm X 100cm (40" X 40"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
61	SW11611650-B/W	CareGUARD* Contrast, 116cm X 116cm (45" X 45"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
62	SW11611660-B/W	CareGUARD* Contrast, 116cm X 116cm (45" X 45"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
63	SW11611675-B/W	CareGUARD* Contrast, 116cm X 116cm (45" X 45"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
64	SW12012050-B/W	CareGUARD* Contrast, 120cm X 120cm (48" X 48"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
65	SW12012060-B/W	CareGUARD* Contrast, 120cm X 120cm (48" X 48"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
66	SW12012075-B/W	CareGUARD* Contrast, 120cm X 120cm (48" X 48"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
67	SW13713750-B/W	CareGUARD* Contrast, 137cm X 137cm (54" X 54"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
68	SW13713760-B/W	CareGUARD* Contrast, 137cm X 137cm (54" X 54"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
69	SW13713775-B/W	CareGUARD* Contrast, 137cm X 137cm (54" X 54"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM
70	SW13718250-B/W	CareGUARD* Contrast, 137cm X 182cm (54" X 72"), 50GSM, Blue/White Bonded, Two Layers, Total GSM: 100 GSM
71	SW13718260-B/W	CareGUARD* Contrast, 137cm X 182cm (54" X 72"), 60GSM, Blue/White Bonded, Two Layers, Total GSM: 120 GSM
72	SW13718275-B/W	CareGUARD* Contrast, 137cm X 182cm (54" X 72"), 75GSM, Blue/White Bonded, Two Layers, Total GSM: 150 GSM

Indications for Use

CareGUARD* Sterilization Wrap is a single-use, non-woven sterilization wrap intended to be sterilized by a health care provider using pre-vacuum steam at 273°F / 134°C for 4 minutes. The CareGUARD* Sterilization Wrap was validated for a dry time of 30 minutes. The CareGUARD* Sterilization wrap is recommended to be used with trays weighing up to 13.7 lbs.

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

Test results validated that CareGUARD* Sterilization wraps allowed sterilization of the enclosed devices by pre-vacuum cycles.

TABLE 2: WRAP BASIS WEIGHT RECOMMENDATIONS FOR PRE-VACUUM STEAM

Basis Weight	Maximum Wrapped Package Content Weight
50 GSM	6.2 kg / 13.7 lbs
60 GSM	
75 GSM	

The following load was used in the Pre-vacuum steam Sterility Maintenance Study:

- 50 GSM: 21 in. x 10 in. x 4 ¾ in. (54 cm x 25 cm x 12 cm) tray containing 13.7 lbs (6.2 kg) of metal mass
The metal mass included surgical instruments used for orthopedic joint replacement.

Technological Characteristics Comparison

TABLE 3: COMPARISON OF PROPOSE AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Manufacturer	Care Essentials Pty Ltd	Halyard Health (Formerly Kimberly Clark Health Care)	Different
510(k) Reference	K213907	K082554	Different
Device Models	50 gsm 60 gsm 75 gsm	H300 H400 H500	Similar
Common name	Sterilization Wrap	Sterilization Wrap	Same
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Class	II	II	Same
Product Code	FRG	FRG	Same
Intended Use	To enclose another medical device that is to	To enclose another medical device that is to be sterilized by a healthcare provider.	Same

	be sterilized by a healthcare provider.		
Indications for Use	<p>CareGUARD* Sterilization Wrap is a single-use, non-woven sterilization wrap intended to be sterilized by a health care provider using pre-vacuum steam at 273°F / 134°C for 4 minutes. The CareGUARD* Sterilization Wrap was validated for a dry time of 30 minutes. The CareGUARD* Sterilization wrap is recommended to be used with trays weighing up to 13.7 lbs.</p> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.</p> <p>Test results validated that CareGUARD* Sterilization wraps allowed sterilization of the enclosed devices by pre-vacuum cycles.</p>	<p>KimGUARD* Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:</p> <ul style="list-style-type: none"> • Pre-vacuum Steam 270°F/132°C for 4 minutes • Ethylene oxide (100%) Concentration: 725 – 735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until opened.</p> <p>The wrap was validated for aeration times for</p> <ul style="list-style-type: none"> • EtO sterilization 8 hours at 55°C or 12 hours at 43.3°C. • Pre-vacuum steam sterilization 20 minutes – Models 100, 200 and 300 30 minutes – Models 400, 500, 600 	Similar
Device Design	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS).	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS).	Same
Wrapping Technique	Sequential/Simultaneous double wrapping	Sequential/Simultaneous double wrapping	Same
Method for bonding SMS layers	Thermal bonding with oval shape pin in angular pattern.	Thermal bonding with round pin, hexagonal, triangle bond pattern (“daisy” pattern).	Similar

Method for bonding between sterilization wraps	If applicable, ultrasonically seamed along two edges.	If applicable, ultrasonically seamed along two edges.	
Material Composition	Polypropylene with blue and white pigments.	Polypropylene with blue and white pigments.	Same
Single Use Device	Yes	Yes	Same
Shelf Life	2 years from date of manufacture	NIL	Similar
Biocompatibility	Applicable parts of ISO 10993 – Biological evaluation of medical devices (see Table 4)	Applicable parts of ISO 10993 – Biological evaluation of medical devices	Same
Maintenance of Package Sterility	Real-time testing following sterilization using pre-vacuum steam supports maintenance of package sterility for 30 days.	Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 30 days.	Similar

Summary of Non-clinical Testing

TABLE 4: SUMMARY OF NON-CLINICAL TESTING

Test	Relevant Standard(s)	Acceptance Criteria	Results
Physical Properties	ISO 11607-1 EN 868-2	Comply with the physical property requirements of ISO 11607-1 and EN 868-2.	The processed and unprocessed CareGUARD* Sterilization Wrap met the acceptance criteria and demonstrated passing results.
Chemical Properties	ISO 11607-1 EN 868-2	Comply with the chemical property requirements of ISO 11607-1 and EN 868-2.	The chemical properties testing met the acceptance criteria and demonstrated passing results.

Biocompatibility	ISO 10093-5 ISO 10993-10	Determine whether the use of the medical device is cytotoxic, skin irritating or skin-sensitizing.	Based on the study, the medical device was found to be non-cytotoxic, non-skin irritating and non-skin sensitizing.
Bacterial Filtration Efficiency (BFE)	ASTM F2101-14	Determining the bacterial filtration efficiency of the sterilisation wrap	Pass
Pre-vacuum Steam			
Sterilization Validation	AS/NZS 4187:2014 ANSI/AAMI/ST8:2013 (R2018) ANSI/AAMI ST79:2017	A pre-vacuum steam sterilization method was validated to a sterility assurance level (SAL) of 10 ⁻⁶	Pass
Sterilant Penetration	AS/NZS 4187:2014 ANSI/AAMI/ST8:2013 (R2018) ANSI/AAMI ST79:2017	The testing details a method used in determining the internal temperature profile for wrapped sterilization packs when processed in a steam sterilization pre-vacuum cycle at 273°F/134°C for 4 minutes.	Testing has demonstrated adequate sterilant penetration
Validation – Dry Time	AS/NZS 4187:2014 ANSI/AAMI/ST8:2013 (R2018) ANSI/AAMI ST79:2017 EN 285:2015+A1:2021	Determination of the proper drying time required.	Test samples meet or exceed the minimum criteria for dry time
Maintenance of Sterility	ISO 11607-1:2019 ANSI/AAMI ST79:2017 AS/NZS 4187:2014 ANSI/AAMI/ST8:2013 EN 285:2015+A1:2021	Determination of the maintenance of sterility for the wrapped loads.	Real-time testing following sterilization using pre- vacuum steam supports maintenance of package sterility for 30 days.

Summary of Clinical Testing

Clinical testing is not applicable to the CareGUARD* Sterilization Wrap.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the CareGUARD* Sterilization Wrap (K213907), is as safe, as effective and performs as well as or better than the legally marketed device identified [Kimberly-Clark* Corporation KIMGUARD* Sterilization Wrap (K082554)].