

January 17, 2023

Winner Medical Co., Ltd.
Mingni Liu
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road,
Loughua District
Shenzhen, Guangdong 518109
China

Re: K221754

Trade/Device Name: Ag Foam Dressing Non-Adhesive (OTC); Ag Foam Dressing Adhesive (OTC);

Silicone Ag Foam Dressing (OTC); Silicone Ag Foam Dressing with Border

(OTC)

Regulatory Class: Unclassified

Product Code: FRO

Dated: November 24, 2022 Received: November 25, 2022

## Dear Mingni Liu:

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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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 <u>Federal Register</u>.

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

K221754 - Mingni Liu Page 2

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 and Part 809); 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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</a>) and CDRH Learn (<a href="https://www.fda.gov/training-and-continuing-education/cdrh-learn">https://www.fda.gov/training-and-continuing-education/cdrh-learn</a>). 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 (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</a>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

# Julie A. Morabito -S

Julie Morabito, 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** 

# DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

# **Indications for Use**

510(k) Number (if known)

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023 See PRA Statement below.

K221754					
Device Name					
Ag Foam Dressing Non-Adhesive, Ag Foam Dressing Adhesive, Silicone Ag Foam Dressing, Silicone Ag Foam Dressing with Border					
Indications for Use (Describe)					
The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.					
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.					

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

#### **Tab #7 510(k) Summary**

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K221754

1. **Date of Submission**: June 08, 2022

#### 2. Submitter Identification

#### Winner Medical Co., Ltd.

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen City, Guangdong Province, 518109, China

Contact Person: Mingni Liu

Position: Regulatory Affairs Specialist

Tel: +86-755 28138888-8822 Fax: +86-755 28134588

Email:2346@winnermedical.com

# 3. Identification of Proposed Device

Trade/Proprietary Name: Ag Foam Dressing Non-Adhesive (OTC)

Ag Foam Dressing Adhesive (OTC) Silicone Ag Foam Dressing (OTC)

Silicone Ag Foam Dressing with Border (OTC)

Common name: Antimicrobial dressing

# **Regulatory Information**

Classification Name: Dressing, Wound, Drug;

Classification: Unclassified;

Product Code: FRO;

Review Panel: General & Plastic Surgery;

# 4. Identification of Predicate Device

Primary Predicate Device:

510(k) Number: K191819

510(K) Summary

Product Name: Ag Foam Dressing Non-Adhesive

Ag Foam Dressing Adhesive

Silicone Ag Foam Dressing

Silicone Ag Foam Dressing with Border

Manufacturer: Winner Medical Co., Ltd.

Secondary Predicate Device:

510(k) Number: K180570

Product Name: Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also

known as Silverlon® Burn Pad Dressing)

Manufacturer: Argentum Medical, LLC

5. Device Description

It is a sterile, single-use dressing, the foam layer contain about 0.25-0.35mg/cm<sup>2</sup> silver. The

dressing absorbs wound exudate and releases silver ions within the dressing in the presence of

wound fluid to help reduce bacterial colonization of the dressing. It also assists in maintaining

a moist environment for optimal wound healing, and allows intact removal.

The devices are available in four configurations:

The basic configuration, Ag Foam Dressing Non-adhesive, consist of a top layer (Vapor

permeable and waterproof polyurethane film); a soft, absorbing polyurethane (PU) antimicrobial

foam contain silver compounds adhered to the top film with acrylic adhesive. The film backing

has the same area as the polyurethane foam layer. The product line is available in different sizes.

A second adhesive configuration, Ag Foam Dressing Adhesive, consists of a top layer (Vapor

permeable and waterproof polyurethane film); a center layer (A thin non-woven and absorbent

polyurethane antibacterial foam pad containing silver compounds adhered to the top film, and

the top film remained border part); a release liner (covered on the foam pad and top film border

part). The product line is available in different sizes.

A third adhesive configuration, Silicone Ag Foam Dressing, consists of a top layer (Vapor

permeable and waterproof polyurethane film); a center layer (Absorbent polyurethane

antibacterial foam pad containing silver compounds adhered to the top film); a wound contact

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layer (Perforated laminate of acrylic adhesive/polyurethane film/silicone gel, where the acrylic adhesive adheres to the top film, and the silicone gel is for skin adherence); a release liner covers on the silicone gel. The product line is available in different sizes.

A forth adhesive configuration, Silicone Ag Foam dressing with Border, consists of a top layer (Vapor permeable and waterproof polyurethane film); a center layer (A supper absorbent fiber pad, a thin non-woven and absorbent polyurethane antibacterial foam pad containing silver compounds adhered to the top film, and the top film remained border part); a wound contact layer (Perforated silicone gel adhered to the center layer and top film); a release liner (covered on the silicone gel).

The dressing has light yellow or light brown appearance and is available in the form of pad and in different sizes packaged in pouches. All dressings can absorb exudates, maintains a moist wound healing environment and has good antibacterial properties. It has been shown that antibacterial effectiveness within the dressing for up to 7 days, as demonstrated in vitro.

Silicone Ag Foam Dressing and Silicone Ag Foam Dressing with Border are sterilized and sold directly to users after sterilized by EtO using conditions validated following ISO 11135-1: 2014. Ag Foam Dressing Non-adhesive and Ag Foam Dressing Adhesive are sterilized and sold directly to users after sterilized by irradiation using conditions validated following ISO 11137-2: 2013.

The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are substantially equivalent in composition, material components, function and performance to Winner's Silicone Ag Foam Dressing (Rx) /Silicone Ag Foam Dressing with Border (Rx)/ Ag Foam Dressing Non-adhesive (Rx) /Ag Foam Dressing Adhesive (Rx) cleared by FDA under 510(k) K191819. The primary purpose of this 510(k) is to allow OTC retail marketing of this dressing. Labeling of the OTC product has been revised to include added directions for use for a non-professional retail population.

#### 6. Indications for use

The Silicone Ag Foam Dressing (OTC) /Silicone Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.

#### 7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate device. Since the proposed device has the same device design as the primary predicate device, the tests performed for the primary predicate device can be leveraged for the proposed device. These tests including: cytotoxicity, skin sensitization, irritation, acute systemic toxicity, pyrogen, implantation and subacute systemic toxicity, bacterial endotoxin, antimicrobial effectiveness test, EO ECH residue test.

The performance test, including antimicrobial effectiveness test, liquid absorbency, waterproofness and moisture vapor transmission rate were conducted on the proposed device.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation.
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11:2017 Biological Evaluation Of Medical Devices- Part 11: Tests For Systemic Toxicity.
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP <85> Bacterial Endotoxins Test

#### 8. Clinical Test Conclusion

No clinical study is included in this submission.

# 9. Substantially Equivalent (SE) Comparison

The proposed devices, Silver Foam Dressings (OTC), are compared with the following Predicate Devices in terms of intended use, mechanism, material, and performance. These data came from commercially product labeling and 510(k) summary.

# • Primary Predicate Device:

510(k) Number: K191819

Product Name: Ag Foam Dressing Non-Adhesive / Ag Foam Dressing Adhesive /

Silicone Ag Foam Dressing / Silicone Ag Foam Dressing with Border, Manufactured by

Winner Medical Co., Ltd.

#### • Secondary Predicate Device:

510(k) Number: K180570

Product Name: Silverlon® Island Wound Dressing, Silverlon® Wound Pad Dressing (also

known as Silverlon® Burn Pad Dressing), Manufactured by Argentum Medical, LLC.

The following table shows similarities and differences of use, design, material, and processing methods between proposed device and two predicate devices.

Table 1 Comparison of intended use and Technological Characteristics

Item	Proposed Device	Primary Predicate Device	Secondary Predicate
		(K191819)	Device (K180570)
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified

Dressing (OTC) //Silicone Ag Foam Dressing with Border (OTC) //Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, super absorbent fiber, non- woven fabrics, Silicone contact layer, super absorbent fiber, non- woven fabrics, Silicone contact layer, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyarethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyarethane film, Polyarethane film, polyarethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyarethane film, Polyarethane film, Polyarethane film, Polyarethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyarethane film, Polyarethane film, Polyarethane film, Polyarethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyarethane film, Polyarethane	T., 4., 4., 4 I I I	The Ciliana A - E	A - E Di	The Court The Court
Ag Foam Dressing with Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism	Intended Use	The Silicone Ag Foam	Ag Foam Dressings are	The Over-The-Counter
Border (OTC)/ Ag Foam Dressing Non-adhesive (OTC) and Ag Foam Dressing Non-adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film polyurethane foam containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Porsesing Ad Silver highly excluding wounds, such as leg and foot ulcers, traumatic and surgical wounds, donor sites, 1st and 2nd degree burns.  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film polyurethane  Antibacterial  Antibacterial  Antibacterial  Portugurethane film or wound fabrics, Silicone contact layer, Release liner  Portugurethane film or woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Portugurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyurethane film or woven fabrics, Silicone contact layer, Release liner  Polyure				
Dressing Non-adhesive (OTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam for count and polyurethane foam containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial Duration  Dressing Adhesive (COTC) are indicated to cover and protect, absorbs on the dictact and protect, absorbs on the cover and protect, and and surgical wounds, such as leg and foot ulcers, pressure ulcers, diabetic foot ulcers, traumatic and surgical wounds, donor sites, 1st and 2nd degree burns.  Polyurethane foam and super absorbent fiber and protect the foam for reducing bacteria colonization in the dressing; Silicone contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane film , polyurethane foam containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial Duration  Drassing are for local mana surgical wounds, donor sites, 1st and 2nd degree burns.  Drassing are for local mana surgical wounds, donor sites, 1st and 2nd egree burns.  Silver onse fot ulcers, pressure titler foot ulcers, traumatic and surgical wounds, donor sites, 1st and 2nd egree burns.  Silver long degree  Drassing are for local mana surgica				
COTC) and Ag Foam Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.    Mechanism		Border (OTC)/ Ag Foam	the management of	Wound Dressing and
Dressing Adhesive (OTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrassions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam effoam containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibac		Dressing Non-adhesive	moderately to highly	Silverlon® Wound Pad
COTC) are indicated to cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, and minor burns.    Mechanism		(OTC) and Ag Foam	exuding wounds, such as	Dressing are for local
cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane folm containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Antibacterial  Antibacterial  Polyurethane fominor cuts, minor abrasions, and manus urgical wounds, donor sites, 1st and 2nd degree burns.  Boto alone and surgical wounds, donor sites, 1st and 2nd degree burns.  Boto alone and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Backing film for waterproof.  Backing film for waterproof.  Material  Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Polyurethane  To days  Polyurethane foam and super absorbent fiber and reducing bacteria colonization in the dressing when activated by moisture. The silver ions in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive;  Nylon fiber coated with metallic silver;  Non-stick polyethylene film laminated pad;  Polyeter fabric coated on the skin-contacting side with acrylic pressure sensitive adhesive;  Release liner  Antibacterial  Polyuration  Polyarethane foam and super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyeter fabric coated on the skin-contacting side with acrylic pressure sensitive adhesive;		Dressing Adhesive	leg and foot ulcers,	management of
cover and protect, absorb wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane folm containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Antibacterial  Polyurethane fominor cuts, minor abrasions, and maintain moisture surgical wounds, donor sites, 1st and 2nd degree burns.  Iminor burns, abrasions and lacerations.  minor burns, abrasions and lacerations.  ### Antibacterial Polyurethane foam and super absorbent fiber and super absorbent fiber and super absorbent fiber and for absorbing liquid; Silver compounds  Folyurethane foam and super absorbent fiber and for absorbing liquid; Silver compounds  Silver compounds  Silver compounds  Silver conspounds  Silver conspoun		(OTC) are indicated to	pressure ulcers, diabetic	superficial wounds,
wound exudate, and maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Antibacterial  Polyarethane film minor abrasions, minor lacerations, minor absorbing liquid; silver coated nylon fiber absorbing liquid; solver compounds present in the foam for reducing bacteria colonization in the dressing; silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Polyuration  Waterial surgical wounds, donor sites, 1st and 2 <sup>nd</sup> degree burns.  Polyurethane foam and super absorbent fiber and super absorbent fiber absorbing liquid; solver absorbing liquid; solver coated on the surgical desire absorbing wound exudate; Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive;  Non-stick polyethylene film metallic silver; Non-stick polyethylene film laminated pad; Polyeter fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner  Antibacterial  Antibacterial  Antibacterial  Antibacterial		cover and protect, absorb	foot ulcers, traumatic and	minor burns, abrasions
maintain moisture balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Matibacterial Antibacterial  Antibacterial Polyurethane foam and super absorbent fiber absorbing wound spersent in the foam and super absorbent fiber absorbing wound spersent in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Polyuration  Polyurethane foam containing silver, Release liner  Antibacterial Polyurethane  Polyurethane foam containing silver, Release liner  Polyurethane Foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane Flam, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane Flam, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane Flam, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane Flam, polyurethane film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure- sensitive adhesive; Release liner.  Polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner		_	surgical wounds, donor	and lacerations.
balance of minor cuts, minor abrasions, minor lacerations, and minor burns.  Mechanism  Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam and super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Polyuratione foam and super absorbent fiber pad for absorbing wound exudate; Silver coated mylon fiber water obsorbing wound exudate; Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Nylon fiber coated with metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial  Antibacterial  Antibacterial  Polyuration  Polyurethane foam and super absorbent fiber wound contact layer, Release liner.  Polyurethane film polyurethane film polyurethane film polyurethane film metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.			_	
minor abrasions, minor lacerations, and minor burns.  Mechanism Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material Polyurethane film , polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material Polyurethane film , polyurethane foam and super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Antibacterial Polyuration  Minor abrasions, minor and super absorbent fiber pad for absorbing liquid; Silver coated nylon fiber wound contact layer delivers antimicrobial beartie and dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Polyurethane film , polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Antibacterial Polyuration  Antibacterial		balance of minor cuts	_	
Iacerations, and minor burns.   Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.   Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner   Polyuratione in the skin-contacting side with a polyuration   Polyurethane film , Polyester fabric coated on the skin-contacting side with a special polyurethane with a contact layer, Release liner   Polyuration   Polyuration   Polyuration   Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner   Polyuration   Polyuration   Polyuration   Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner   Polyuration   Polyuration   Polyuration   Polyuration   Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.   Polyaster fabric coated on the skin-contacting side with acrylic pressure-se			ouris.	
Mechanism		·		
Mechanism Polyurethane foam and super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Antibacterial  Antibacterial  Polyurethane foam and super absorbent fiber pad for absorbing wound exudate; Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive: Non-stick polyethylene film , polyurethane foam and super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Polyuration Polyur				
super absorbent fiber pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Duration  Silver compounds Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Polyurethane film , polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Duration  Silver coated nylon fiber wound contact layer delivers antimicrobial silver sollevers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Material  Polyurethane film , polyurethane film , polyurethane film , polyurethane metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days  7 days	Marka		D-1	T: 1 C
pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Pad for absorbing liquid; Silver compounds present in the foam for reducing bacteria colonization in the delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self- adhesive Non-stick polyethylene film laminated pad; Polyusethane foam contact layer, Release liner Release liner  Antibacterial Duration  Pad for absorbing liquid; Silver compounds Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self- adhesive  how acteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self- adhesive  how acteria held in the dressing and provide an antimicrobial silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure- sensitive adhesive; Release liner.  7 days  7 days  7 days	Mechanism	·	,	-
Silver compounds present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Duration  Silver compounds present in the foam for reducing bacteria (aclivers antimicrobial silver ions in the dressing when activated by silver ions in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Polyurethane film , polyurethane film , polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Duration  Silver coated nylon fiber wound contact layer delivers antimicrobial silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dressing when activated by moisture. The silver ions in the dres		_	_	G
present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film , polyurethane foam containing silver, super absorbent fiber, non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Duration  Present in the foam for reducing bacteria colonization in the delivers antimicrobial silver ions in the dressing when activated by silver ions in the dressing kill wound because in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Non-stick polyethylene film , polyurethane film , metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner  Antibacterial Duration  Present in the foam for reducing bacteria colonization in the delivers antimicrobial silver contact layer dressing when activated by Silicone soft contact layer delivers antimicrobial silver ions in the dressing when activated by Silicone soft contact layer delivers antimicrobial silver ions in the dressing when activated by  Silicone soft contact layer dressing;  Polyurethane film for waterproof.  Polyurethane film obacterial provide an antimicrobial silve waterproof.  Polyurethane film , polyurethane film , metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days  7 days		1		, and the second
reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Paterial  Polyuration  Ratibacterial  Polyuration  Producing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Polyurethane film , metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure- sensitive adhesive; Release liner.  Antibacterial Duration  Adays		•	•	<u> </u>
colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Duration  Colonization in the dressing when activated by moisture. The silver ions in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Nylon fiber coated with metallic silver; Non-stick polyethylene film laminated pad; Polyster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner  7 days		1 *	-	•
dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Duration  dressing; Silicone soft contact layer for self-adhesive; Silicone soft contact layer for self-soft contact layer in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Nylon fiber coated with metallic silver; Non-stick polyethylene film laminated pad; Polyster fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner  Antibacterial Duration  dressing; Silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Antibacterial Duration  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Are silicone soft contact layer for self-adhesive; Silicone contact layer, Release liner  Antibacterial Duration		reducing bacteria	reducing bacteria	delivers antimicrobial
Silicone soft contact layer for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  Jouration  Silicone soft contact layer for self-adhesive; in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Nylon fiber coated with metallic silver; Non-stick polyethylene film non-woven fabrics, Silicone contact layer, Release liner  Antibacterial  Antibacterial  Antibacterial  Antibacterial  Silicone soft contact layer for self-adhesive; Sacking film for waterproof.  Polyurethane film oprotect the wound bed; Top layer for self-adhesive in the dressing kill wound bacteria held in the dressing and provide an antimicrobial bacteria held in the dressing and provide an antimicrobial bacteria held in the dressing kill wound bacteria held in the dressing and provide an antimicro		colonization in the	colonization in the	silver ions in the dressing
for self-adhesive; Backing film for waterproof.  Material  Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial  7 days  Por self-adhesive; backing film for waterproof.  Backing film for bacteria held in the dressing kill wound bacteria held in the dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Nylon fiber coated with metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial  7 days  7 days  7 days		dressing;	dressing;	when activated by
Backing film for waterproof.  Backing film for dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive;  Non-stick polyethylene film laminated pad;  Polyurethane film , polyurethane film , metallic silver;  Non-stick polyethylene film laminated pad;  Polyurethane film , polyurethane film , metallic silver;  Non-stick polyethylene film laminated pad;  Polyurethane film , metallic silver;  Non-stick polyethylene film adhesive;  Release liner film antimicrobial barrier to protect the wound bed;  Top layer for self-adhesive  Nylon fiber coated with metallic silver;  Non-stick polyethylene film antimicrobial barrier to protect the wound bed;  Top layer for self-adhesive  Nylon fiber coated with metallic silver;  Non-stick polyethylene film , m		Silicone soft contact layer	Silicone soft contact layer	moisture. The silver ions
waterproof.  waterproof.  waterproof.  waterproof.  waterproof.  waterproof.  dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive  Material  Polyurethane film, polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Release liner  Antibacterial Duration  waterproof.  dressing and provide an antimicrobial barrier to protect the wound bed; Top layer for self-adhesive Silicone containing silver, super absorbent fiber, film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner  7 days  7 days  7 days		for self-adhesive;	for self-adhesive;	in the dressing kill wound
Material Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner Antibacterial Duration Polyurethane In polyurethane adhesive adhesive metallic silver; hon-stick polyethylene film laminated pad; hon-stick polyethylene film laminated pad; hon-woven fabrics, silicone contact layer, polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.		Backing film for	Backing film for	bacteria held in the
Material Polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner Antibacterial Duration Polyurethane In polyurethane adhesive adhesive metallic silver; hon-stick polyethylene film laminated pad; hon-stick polyethylene film laminated pad; hon-woven fabrics, silicone contact layer, polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.		waterproof.	waterproof.	dressing and provide an
Material Polyurethane film, polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner  Antibacterial 7 days 7 days  Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days 7 days 7 days 7 days			-	
Material Polyurethane film, polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner  Antibacterial 7 days 7 days  Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days 7 days 7 days 7 days				protect the wound bed:
Material Polyurethane film, polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner  Antibacterial Duration  Polyurethane film, polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; non-woven fabrics, Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days  7 days  7 days				•
Material Polyurethane film, polyurethane film, polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner Polyurethane film, metallic silver; Non-stick polyethylene film laminated pad; non- woven fabrics, Silicone contact layer, Release liner Release liner With acrylic pressuresensitive adhesive; Release liner.  Antibacterial 7 days 7 days 7 days 7 days				
polyurethane polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner Polyurethane foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner Release liner Release liner Polyurethane metallic silver; Non-stick polyethylene film laminated pad; Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Antibacterial 7 days 7 days 7 days 7 days	Material	Polyurethane film	Polyurethane film	
foam containing silver, super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Duration  foam containing silver, super absorbent fiber, non- woven fabrics, Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days  7 days		_	=	
super absorbent fiber, non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Duration  Super absorbent fiber, non- woven fabrics, non- woven fabrics, Silicone contact layer, Release liner  Super absorbent fiber, non- woven fabrics, Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days  7 days		1 •		·
non- woven fabrics, Silicone contact layer, Release liner  Antibacterial Duration  Non- woven fabrics, Silicone contact layer, Silicone contact layer, Release liner Silicone contact layer, Release liner  Antibacterial Silicone contact layer, Release liner  Todays  Antibacterial Todays  Todays  Polyester fabric coated on the skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  Todays  Todays		_	_	
Silicone contact layer, Release liner  Release liner  Release liner  Antibacterial Duration  Silicone contact layer, Release liner  Silicone contact layer, Release liner  The skin-contacting side with acrylic pressure-sensitive adhesive; Release liner.  7 days  7 days  7 days		_	_	•
Release liner Release liner with acrylic pressure- sensitive adhesive; Release liner.  Antibacterial 7 days 7 days 7 days  Duration 7 days 7 days			·	
sensitive adhesive; Release liner.  Antibacterial 7 days 7 days 7 days  Duration 7 days 7 days		1	-	_
Antibacterial 7 days 7 days 7 days Duration Release liner. 7 days 7 days		Kelease liner	Kelease liner	· =
Antibacterial 7 days 7 days 7 days Duration 7 days				
Duration				
		7 days	7 days	7 days
Single Use Yes Yes Yes				
	Single Use	Yes	Yes	Yes

Sterilization	Ag Foam Dressing Non-	Ag Foam Dressing Non-	Sterilization by: EtO.
	Adhesive (OTC) &	Adhesive &	SAL: 10 <sup>-6</sup>
	Ag Foam Dressing	Ag Foam Dressing	
	Adhesive(OTC)	Adhesive sterilization by	
	sterilization by gamma	gamma irradiation;	
	irradiation;	Silicone Ag Foam	
	Silicone Ag Foam	Dressing &	
	Dressing (OTC) &	Silicone Ag Foam	
	Silicone Ag Foam	Dressing with Border	
	Dressing with Border	sterilization by EtO.	
	(OTC) sterilization by	SAL: 10 <sup>-6</sup>	
	EtO.		
	SAL: 10 <sup>-6</sup>		
Biocompatibil	Biocompatibility in	Biocompatibility in	Biocompatibility in
ity	accordance to 10993-	accordance to 10993-	accordance to 10993-
	1(breached or	1(breached or	1(breached or
	compromised surfaces	compromised surfaces	compromised surfaces
	with prolonged	with prolonged	with prolonged
	contact(>24h to 30d))	contact(>24h to 30d))	contact(>24h to 30d))

The compositions, materials, function and performance of the proposed devices are substantially equivalent to the primary predicate devices. The proposed devices are for OTC use, therefore their intended use is substantially equivalent to the secondary predicate device, Silverlon® Island Wound Dressing (for OTC use)and Silverlon® Wound Pad Dressing (for OTC use), while the primary predicate device is for prescription use. All of these devices pad for absorbing wound exudate, contain silver ions to reduce bacteria colonization in the dressing, and top layer for self-adhesive. In order to address the questions raised from differences, biocompatibility tests according to 10993-1 were conducted. These are no new questions of the safety and efficacy raised.

#### 10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.