

<b>File name:</b>	Declaration of Conformity	
<b>Product name:</b>	Sterilization Pouch and Roll	
<b>Class:</b>	I	
<b>EMDN code(s):</b>	S010101	
<b>Basic UDI-DI:</b>	69735630600069V	
<b>Author:</b>	Parker Lee	
<b>Approval:</b>	Patty Chen	
<b>File number:</b>	SSRD-02-11	
<b>Revision:</b>	B/3	
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<b>Date:</b>	Oct 19 <sup>th</sup> , 2022	
<b>Revision history record</b>		
<b>Version</b>	<b>Revision content simple descriptions</b>	<b>Effective date</b>
A/0	New version issued	Mar. 1 <sup>th</sup> , 2019
B/0	According to the new regulation MDR (EU)2017/745 update information	June. 10 <sup>th</sup> , 2021
B/1	Company address changed; Update testing Standard and quality system standard	Feb.17 <sup>th</sup> ,2022
B/2	Update Standard Version	Mar.30 <sup>th</sup> ,2022
B/3	Update Standard Version	Oct.19 <sup>th</sup> , 2022



Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd

## Declaration of Conformity

**Manufacturer:** Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.

**Address:** 6A01, Block 1, Ahoke Plaza, Daling Community, Minzhi Street, Longhua District, 518109 Shenzhen City, Guangdong, PEOPLES REPUBLIC OF CHINA

**http://**www.safesecuremic.com/

**SRN:** CN-MF-000011843

**Product Name:** Sterilization Pouch and Roll

**Basic UDI-DI:** 69735630600069V

**Model:** See Annex I for details

**EMDN Code:** S010101

**Classification:** Class I

**Rule:** According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745

**Conformity Assessment Route:** Annex II + Annex III of (EU) MDR 2017/745

**Intended Use:** It is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam, ethylene oxide (EtO) and plasma sterilization.

We hereby declare that above mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

**EU Authorized Representative:**

Shanghai International Holding Corp.GmbH (Europe)

**Address:** Eiffestrasse 80,20537 Hamburg Germany



**I, the undersigned, hereby declare that the specified medical device(s) meet the provisions of the following standards.**

**Testing Standard Applied:**

EN ISO11607-1:2020	EN ISO11607-2:2020	EN 868-5:2018	ISO 11140-1-2014
EN ISO10993-1:2020	ISO10993-5:2009	ISO10993-10:2021	ISO 10993-23:2021
ASTM F 1929:2015	ASTM F88/F88M-21	ASTM F1980-21	

**Quality System Standard Applied:**

ISO 13485:2016	ISO 14971:2019	ISO 15223-1:2021	(EU) MDR2017/745
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**Place, Date of Issue:**

2022-10-19  
ShenZhen City

**Person Responsible for Regulatory Compliance:**

Signature:         Pooy Chen        

*The signature is signed on behalf of Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.*



Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd

**ANNEX I:**

The follow tables list the available model numbers of the Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd Sterilization Pouch and Roll.

Table 1: Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd Medical Grade Paper Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions	
			Width	Length
ABHSP10	HEAT SEAL STERILIZATION PAPER POUCH	Steam or Ethylene Oxide	1.75"~30"	2"~30"
ABHSP11	HEAT SEAL STERILIZATION PAPER TUBING POUCH	Steam or Ethylene Oxide	1.75"~30"	NA
ABSSP10	SELF SEAL STERILIZATION PAPER POUCH	Steam or Ethylene Oxide	1.75"~30"	2"~30"

Table 2: Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd Tyvek Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions(mm)	
			Width (mm)	Length (mm)
ABHST10	HEAT SEAL STERILIZATION TYVEK POUCH	Ethylene Oxide or Plasma sterilization	1.75"~30"	2"~30"
ABHST11	HEAT SEAL STERILIZATION TYVEK TUBING POUCH	Ethylene Oxide or Plasma sterilization	1.75"~30"	NA
ABSST10	SELF SEAL STERILIZATION TYVEK POUCH	Ethylene Oxide or Plasma sterilization	1.75"~30"	2"~30"

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6A01, Block 1, Ahoke Plaza, Daling Community, Minzhi Street, Longhua District, 518109 Shenzhen City, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Name	Product Code	SS Model
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 9¼ in. ▪ 100mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48497	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 10½ in. ▪ 100mm x 270mm ▪ Flat Pack ▪ STEAM/EO	48498	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 11¼ in. ▪ 100mm x 300mm ▪ Flat Pack ▪ STEAM/EO	48499	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 11¼ in. ▪ 150mm x 300mm ▪ Flat Pack ▪ STEAM/EO	48506	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 14¼ in. ▪ 150mm x 380mm ▪ Flat Pack ▪ STEAM/EO	48507	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 15¼ in. ▪ 150mm x 400mm ▪ Flat Pack ▪ STEAM/EO	48508	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 8 in. x 15¼ in. ▪ 205mm x 400mm ▪ Flat Pack ▪ STEAM/EO	48510	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 9¼ in. x 14¼ in. ▪ 250mm x 380mm ▪ Flat Pack ▪ STEAM/EO	48512	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 9¼ in. x 19¼ in. ▪ 250mm x 500mm ▪ Flat Pack ▪ STEAM/EO	48513	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 2¼ in. x 7 ¾ in. ▪ 75mm x 200mm ▪ Flat Pack ▪ STEAM/EO	48518	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 2¼ in. x 9 ¾ in. ▪ 75mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48519	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 656' ▪ 100mm x 200m ▪ Flat Reel ▪ STEAM/EO	48521	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 656' ▪ 150mm x 200m ▪ Flat Reel ▪ STEAM/EO	48522	ABHST11
Sterilization Pouch ▪ Heat Seal Paper ▪ 7¼ in. x 656' ▪ 200mm x 200m ▪ Flat Reel ▪ STEAM/EO	48523	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 9¼ in. x 656' ▪ 250mm x 200m ▪ Flat Reel ▪ STEAM/EO	48524	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 1¼ in. x 656' ▪ 50mm x 200m ▪ Flat Reel ▪ STEAM/EO	48525	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 2¼ in. x 656' ▪ 75mm x 200m ▪ Flat Reel ▪ STEAM/EO	48526	ABHSP11
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 7¼ in. x 328' ▪ 200mm x 100m ▪ Flat Reel ▪ PLASMA	48535	ABHST11
Sterilization Pouch ▪ Self Seal Paper ▪ 3¼ in. x 11¼ in. ▪ 100mm x 300mm ▪ Flat Pack ▪ STEAM/EO	48538	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 5 in. x 10½ in. ▪ 130mm x 270mm ▪ Flat Pack ▪ STEAM/EO	48540	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 7¼ in. x 13¼ in. ▪ 200mm x 350mm ▪ Flat Pack ▪ STEAM/EO	48541	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 8¼ in. x 16¼ in. ▪ 225mm x 420mm ▪ Flat Pack ▪ STEAM/EO	48542	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 11¼ in. x 19¼ in. ▪ 300mm x 500mm ▪ Flat Pack ▪ STEAM/EO	48546	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 3½ in. x 7¼ in. ▪ 90mm x 200mm ▪ Flat Pack ▪ STEAM/EO	48549	ABSSP10

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Sterilization Pouch ▪ Self Seal Paper ▪ 3½ in. x 9¼ in. ▪ 90mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48550	ABSSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 11¼ in. x 656' ▪ 300mm x 200m ▪ Flat Reel ▪ STEAM/EO	48555	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 15½ in. x 656' ▪ 400mm x 200m ▪ Flat Reel ▪ STEAM/EO	48556	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 19½ in. x 328' ▪ 500mm x 100m ▪ Flat Reel ▪ STEAM/EO	48557	ABHSP11
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 13¼ in. ▪ 150mm x 350mm ▪ Flat Pack ▪ STEAM/EO	48558	ABHSP10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 5¼ in. x 328' ▪ 150mm x 100m ▪ Flat Reel ▪ PLASMA	48534	ABHST11
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 328' ▪ 150mm x 50mm x 100m ▪ Gusseted Reel ▪ STEAM/EO	48494	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 1¼ in. x 15¼ in. ▪ 150mm x 50mm x 400mm ▪ Gusseted Pack ▪ STEAM/EO	48492	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 7¼ in. x 2 in. x 15¼ in. ▪ 200mm x 55mm x 400mm ▪ Gusseted Pack ▪ STEAM/EO	48493	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 5¼ in. ▪ 100mm x 150mm ▪ Flat Pack ▪ STEAM/EO	48495	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 7¼ in. ▪ 100mm x 200mm ▪ Flat Pack ▪ STEAM/EO	48496	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 14¼ in. ▪ 100mm x 380mm ▪ Flat Pack ▪ STEAM/EO	48500	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 15¼ in. ▪ 100mm x 400mm ▪ Flat Pack ▪ STEAM/EO	48501	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 3¼ in. x 20¼ in. ▪ 100mm x 520mm ▪ Flat Pack ▪ STEAM/EO	48502	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 4½ in. x 15¼ in. ▪ 120mm x 400mm ▪ Flat Pack ▪ STEAM/EO	48503	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 7¼ in. ▪ 150mm x 200mm ▪ Flat Pack ▪ STEAM/EO	48504	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 5¼ in. x 10½ in. ▪ 150mm x 270mm ▪ Flat Pack ▪ STEAM/EO	48505	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 7¼ in. x 24 in. ▪ 200mm x 610mm ▪ Flat Pack ▪ STEAM/EO	48509	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 8½ in. x 11¼ in. ▪ 220mm x 300mm ▪ Flat Pack ▪ STEAM/EO	48511	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 11¼ in. x 19¼ in. ▪ 300mm x 500mm ▪ Flat Pack ▪ STEAM/EO	48514	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 16½ in. x 19¼ in. ▪ 420mm x 500mm ▪ Flat Pack ▪ STEAM/EO	48515	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 1¼ in. x 9¼ in. ▪ 50mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48516	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 2¼ in. x 5¼ in. ▪ 75mm x 150mm ▪ Flat Pack ▪ STEAM/EO	48517	ABHSP10
Sterilization Pouch ▪ Heat Seal Paper ▪ 2¼ in. x 11¼ in. ▪ 75mm x 300mm ▪ Flat Pack ▪ STEAM/EO	48520	ABHSP10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 3¼ in. x 10 in. ▪ 100mm x 260mm ▪ Flat Pack ▪ PLASMA	48527	ABHST10

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Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 5¼ in. x 12.50 in. ▪ 150mm x 320mm ▪ Flat Pack ▪ PLASMA	48528	ABHST10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 7¼ in. x 15.75 in. ▪ 200mm x 400mm ▪ Flat Pack ▪ PLASMA	48529	ABHST10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 7¼ in. x 19.50 in. ▪ 200mm x 500mm ▪ Flat Pack ▪ PLASMA	48530	ABHST10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 7¼ in. x 25¼ in. ▪ 200mm x 650mm ▪ Flat Pack ▪ PLASMA	48531	ABHST10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 2¾ in. x 8¼ in. ▪ 75mm x 210mm ▪ Flat Pack ▪ PLASMA	48532	ABHST10
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 3¼ in. x 328' ▪ 100mm x 100m ▪ Flat Reel ▪ PLASMA	48533	ABHST11
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 9¼ in. x 328' ▪ 250mm x 100m ▪ Flat Reel ▪ PLASMA	48536	ABHST11
Sterilization Pouch ▪ Heat Seal Tyvek® ▪ 2¼ in. x 328' ▪ 75mm x 100m ▪ Flat Reel ▪ PLASMA	48537	ABHST11
Sterilization Pouch ▪ Self Seal Paper ▪ 3¼ in. x 13¼ in. ▪ 100mm x 350mm ▪ Flat Pack ▪ STEAM/EO	48539	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 9¼ in. x 13¼ in. ▪ 250mm x 350mm ▪ Flat Pack ▪ STEAM/EO	48543	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 9¼ in. x 15¼ in. ▪ 250mm x 400mm ▪ Flat Pack ▪ STEAM/EO	48544	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 11¼ in. x 17¼ in. ▪ 300mm x 450mm ▪ Flat Pack ▪ STEAM/EO	48545	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 1¼ in. x 9¼ in. ▪ 50mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48547	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 3½ in. x 5 in. ▪ 90mm x 130 mm ▪ Flat Pack ▪ STEAM/EO	48548	ABSSP10
Sterilization Pouch ▪ Self Seal Tyvek® ▪ 5¼ in. x 11¼ in. ▪ 150mm x 300mm ▪ Flat Pack ▪ PLASMA	48551	ABSST10
Sterilization Pouch ▪ Self Seal Tyvek® ▪ 5¼ in. x 12½ in. ▪ 150mm x 320mm ▪ Flat Pack ▪ PLASMA	48552	ABSST10
Sterilization Pouch ▪ Self Seal Tyvek® ▪ 7¼ in. x 15¼ in. ▪ 200mm x 400mm ▪ Flat Pack ▪ PLASMA	48553	ABSST10
Sterilization Pouch ▪ Self Seal Tyvek® ▪ 2¼ in. x 7¼ in. ▪ 75mm x 200mm ▪ Flat Pack ▪ PLASMA	48554	ABSST10
Sterilization Pouch ▪ Self Seal Paper ▪ 5 in. x 9¼ in. ▪ 130mm x 250mm ▪ Flat Pack ▪ STEAM/EO	48559	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 3½ in. x 9 in. ▪ 90mm x 230mm ▪ Flat Pack ▪ STEAM/EO	48560	ABSSP10
Sterilization Pouch ▪ Self Seal Paper ▪ 6¼ in. x 12¼ in. ▪ 175mm x 330mm ▪ Flat Pack ▪ STEAM/EO	48561	ABSSP10