



## Description

MPACK® 'PLASMA' Sterilization Packaging range is a series of see-through heat-sealable pouches and reels intended for use as packing material for medical devices for sterilization by gas plasma and vaporized hydrogen peroxide.

With the use of proper class of indicators, MPACK® 'PLASMA' sterile barrier products are also compatible with other methods of low temperature sterilization (such as EO sterilization).

MPACK® 'PLASMA' sterile barrier products are constructed of a high-grade uncoated Tyvek® \* non-woven polyethylene medical fabric and a clear high-strength multi-layer laminate film.

## Key features

- A well-thought-through design:
  - Reinforced chevron seal at the opening side to preserve the seal from any damage by the instrument.
  - Corner tack seals prevent corners from curling after sterilization and dust from collecting at the opening seal (reducing the risk of contamination).
  - All prints outside the packing area to prevent possible impact on paper porosity and ink offset.
  - Easy-to-open thumb notch preserving sufficient finger lift.
- Uncoated Tyvek® 1073B provides the highest level of protection, making it the ideal choice for medical device packaging that requires high strength and superior microbial barrier.
- Superior multilayer film puncture and abrasion resistance reducing the risk of pinholes.
- Transparent see-through film allowing quick detection of pinholes or tears.
- Clean peel: the triple band ribbed seal is designed with optimum strength and width to prevent bursting while allowing excellent peel-ability for clean, fiber-free opening and aseptic presentation of the product.

Sales Unit: Dispenser/Box.

## Range

Code	Description	Size	Units/Dispenser	Dispensers/Box	Units/Box
1501	PLASMA STERILIZATION POUCHES, flat, heat seal	75x200mm	200pcs	24	4,800pcs
1502	PLASMA STERILIZATION POUCHES, flat, heat seal	100x270mm	200pcs	12	2,400pcs
1503	PLASMA STERILIZATION POUCHES, flat, heat seal	150x300mm	200pcs	12	2,400pcs
1504	PLASMA STERILIZATION POUCHES, flat, heat seal	160x450mm	200pcs	6	1,200pcs
1505	PLASMA STERILIZATION POUCHES, flat, heat seal	250x500mm	200pcs	4	800pcs
1506	PLASMA STERILIZATION POUCHES, flat, heat seal	320x550mm	100pcs	4	400pcs
1507	PLASMA STERILIZATION POUCHES, flat, heat seal	200x400mm	200pcs	4	800pcs
1508	PLASMA STERILIZATION POUCHES, flat, heat seal	350x750mm	100pcs	4	400pcs
1509	PLASMA STERILIZATION POUCHES, flat, heat seal	250x380mm	200pcs	4	800pcs
1510	PLASMA STERILIZATION POUCHES, flat, heat seal	160x600mm	100pcs	8	800pcs
1511	PLASMA STERILIZATION POUCHES, flat, heat seal	205x380mm	200pcs	4	800pcs

(\* Tyvek® is registered trademark of DuPont™)

## Regulations

<b>Compliance with legal requirements:</b>	Medical Devices Regulation 2017/745, Class I. CE marked. FDA compliant.
<b>Compliance with product quality standards:</b>	ISO 11140-1:2014, ISO 11607-1:2019, ISO 11607-2:2019 and EN 868-5:2018.
<b>Label information and packaging compliance:</b>	EN ISO 15223-1 and EN 1041
<b>REACH regulation:</b>	The product covered by this data sheet does not contain carcinogenic, mutagenic or toxic substances, including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by the European Chemicals Agency (ECHA).

The product complies with legal requirements for medical devices. It is manufactured under ISO 13485 quality assurance standard.



## Materials

Product Part	Raw Material & Characteristic
Top web	75 gsm Tyvek® 1073B Medical Packaging Material made of high-density polyethylene (HDPE), Non-coated. Elementary Chlorine Free. Approved for EN 868-3 Process indicators.
Laminate film web	Clear PET/PE composite multi-layer film (12 µm polyester laminated to 45 µm "shatter less" Polyethylene).
Type I Process indicators	Toxic-free, lead-free process Type I indicators for hydrogen peroxide sterilization. Compliant with ANSI/AAMI/ISO 11140-1 Sterilization of healthcare products- Chemical indicators- Part 1: General requirements. Provides distinct color change when exposed to H <sub>2</sub> O <sub>2</sub> :  <span style="border: 1px solid black; padding: 2px;">VH2O2</span> : switch from green to yellow.
Dispenser pack	White paper board
Transport box	Corrugated paper + Kraft paper
Packing Tape	Transparent, PVC-free


## Warnings and Recommendations

Warnings	The product is single use. If reused performance of product may deteriorate, cross contamination may occur.
<b>Sealing parameters</b>	Recommended sealing temperature is 120-140°C, depending on set pressure and time.
<b>Storage Recommendation</b>	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sun light and other intensive light sources.
<b>Disposal Recommendation</b>	Dispose in accordance with local regulations.
<b>Shelf Life</b>	Shelf Life of Unprocessed Pouches/Rolls: 3 years. Maintains sterility for 180 days after sterilization.



**Shanghai Jianzhong Medical Packaging Co., Ltd.**

Bldg16, 789# Puxing Rd, Minhang Dist, Shanghai 201114, China

 MedNet EC-REP GmbH, Borkstrasse 10, 48163 Münster, Germany

Basic UDI-DI: 697462348300153P

Importer: OneMed Sverige AB

Tagenevägen 29, 425 37 Hisings Kärra, Sweden

MPACK® is registered trademark of Shanghai Jianzhong Medical Packaging Co., Ltd.

Tyvek® is registered trademark of DuPont™.