PMSSteripack

TYVEK REELS & POUCHES PRODUCT HANDBOOK

PMS

Introduction

PMS Product Handbook Series are prepared to provide you complete and detailed information about PMS products.

This Product Handbook content is specific to PMSSteripack branded Tyvek sterilization reels and pouches. Their intended use, properties, incoming materials used during manufacturing and applied quality control tests are explained in detail.

The final pages contain quality certificates, test reports from independent laboratories and product related documentation.

Contents

About PMS

PMS is an international producer of sterilization consumables and devices. Since 1997, it has been providing efficient, reliable and flexible solutions for health institutions and medical device manufacturers with its wide product range.

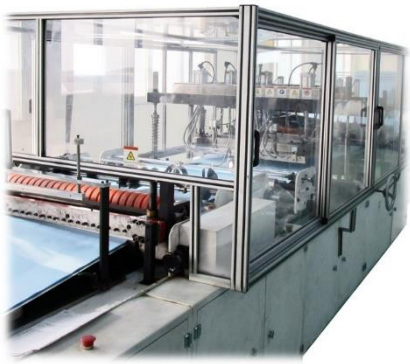
PMSSteripack
PMS Steri-seal
PMS Steri-test

PMS, with the core values it owes and with the conscious of adding value to life by improving product safety for patients, for operators and for the environment with a respect to legal necessities, continues to endeavor for better, improvement and innovation to best serve for all the parts of healthcare services. These values lead PMS to invest on quality, research, development and innovation.

Operating in more than 77 countries in five continents and with production plants in international standards in Turkey and with distribution center in Germany, PMS is a reliable partner with its strategic global collaborations and with its competitive and innovative approach.

For further information: www.pmsmedikal.com

Manufacturing Process



PMSSteripack Tyvek sterilization packaging are manufactured in the Mersin Free Zone Plant of PMS. The plant is ISO 9001 and ISO 13485 certified. As a requirement for certification, the plant has an established Quality System Manual.

PMS strictly complies with the environmental, health and safety regulations in force and the production plant conforms with Clean Room HVAC System Performance Qualifications according to ISO14644-1. The regulations and norms of standards at all level are followed from purchase of raw materials to the shipment of final PMSSteripack branded products

As a requirement of ISO 11607-2 all equipment, machines and processes used for manufacturing of PMSSteripack products are validated. Standard Operation Procedure (SOP), general validation plan and IQ, OQ and PPQ plans and reports for manufacturing equipment are frequently updated and revised by our Quality Assurance Department.

- Annex 1 | ISO 9001 Certification
- Annex 2 | ISO 13485 Certification

In-House Laboratory

PMS expanded its in-house laboratory and invested in new testing devices to provide state-of-the-art product quality control. A wide range of sterilization packaging tests required by related product standards are applied in our new laboratory by specialized and trained personnel.

With a new investment in a Steam Resistometer from the company Fedegari, PMS is now able to test chemical indicator performance according ISO 11140-1.

Resistometers are very accurate and computerized test autoclaves with adjustable sterilization parameters specially designed for biological and chemical indicator testing.

According ISO 11140-1, chemical indicator performance tests must be done in ISO 18472 conformed resistometers.

1. Product Description

PMSSteripack Tyvek sterilization reels and pouches are registered under Class 1 as accessories in compliance with the European Medical Device Directive 93/42/EEC with the amendment of 2007/47/EC. The compliance with the directive is shown by CE mark printed on the shipping carton labels.

- Annex 3 | CE Declaration of Conformity

PMSSteripack Tyvek sterilization reels with Tyvek 1059B grade also meets the requirements of Class 2 according to US FDA 510K

- Annex 4 |FDA 510K Clearance

PMSSteripack Tyvek sterilization packaging is constructed of transparent multilayer PET/PE copolymer film web and Tyvek web in compliance with EN 868-9. Chemical process indicator for H2O2 plasma sterilization is applied on the Tyvek surface for intended sterilization methods.

- Annex 5 | TSE EN 868-5 Certification

Standard PMSSteripack Tyvek sterilization packaging is constructed of Tyvek 2FS with H2O2 plasma chemical process indicator and PET/PE film web.

PMSSteripack Tyvek sterilization packaging is available with Tyvek 2FS, Tyvek 1059B and Tyvek 1073B grades with selectable imprinted chemical process indicator for hydrogen peroxide, ethylene oxide, formaldehyde and gamma sterilization methods. For additional product design requests please contact us at pms@pmsmedikal.com or through your customer representative responsible for your area.

- Annex 6 | Technical Data Sheet Sterilization Reel (2FS)
- Annex 7 | Technical Data Sheet Sterilization Pouch (2FS)
- Annex 8 | Technical Data Sheet Sterilization Pouch (1059B)
- Annex 9 | Technical Data Sheet Sterilization Pouch (1059B)
- Annex 10 | Technical Data Sheet Sterilization Reel (1073B)
- Annex 11 | Technical Data Sheet Sterilization Pouch (1073B)

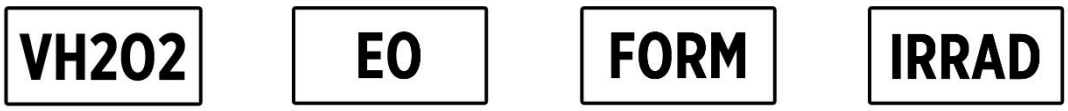
1.1 Intended Use

PMSSteripack Tyvek sterilization reels and pouches are intended for use at packaging of medical devices to be sterilized in low temperature hydrogen peroxide sterilizers with and without plasma stages. Sterilization packaging will maintain its sterility until point of use.

1.2 Sterilization Method

PMSSteripack Tyvek sterilization reels and pouches are designed to be used at low temperature hydrogen peroxide sterilizers. The sterilization packaging provides a protection of the medical device from contamination of bacteria by its high and proven microbial barrier properties and will keep its sterility after successful sterilization until use of the sterilized medical device.

PMSSteripack Tyvek sterilization packaging is also suitable for ethylene oxide, formaldehyde and gamma sterilization methods. To ensure optimum sterility conditions, instructions for use, handling and storage condition recommendations should be taken in consideration and followed.



1.3 Characteristics of the Packaging

PMSSteripack Tyvek sterilization reels and pouches are designed, produces and distributed to provide highest quality standards.

The main characteristics of the packaging are;

- 3 independent seal lines
- Tear free 5 layers PET/PE film web
- Clean peel for aseptic presentation
- Proven microbial barrier properties
- Lead free water based chemical indicator
- Clear and accurate indicator color change
- Wide sealing temperature window (100°C - 120°C)
- Compatible with all Low Temperature Hydrogen Peroxide Sterilization Systems
- Wide range of product sizes and types

1.4 Instructions for Use

PMSSteripack Tyvek sterilization pouches are ready for use. Tyvek sterilization reels need to be cut to required length and sealed at one end to form a ready to fill pouch.

1) Sharp ends of instruments must be covered with an instrument protector to prevent puncturing or cutting.
2) The medical device to be sterilized must be placed in the pouch and it should not be filled more than 75% of its capacity.
3) A gap of minimum 1.5cm between the material and each seal edge of the pouch must be left for a smooth airflow.
4) Before sealing, as much air as possible must be removed from the pouch.

5) The filled pouch has to be sealed with a calibrated and validated heat sealer according to the manufacturer's recommendation. PMSSteripack Tyvek sterilization packaging is suitable for sealing between 100°C up to 120°C. Strength of the seal must assure a clean peel.
6) During the handling seal stress must be avoided by filling the pouch horizontally or by working on a flat surface.
7) When loading into the sterilizer the pouches have to be placed into the basket in a way that film faces film and paper side faces paper side.
8) Sterilization pouches should be put upright in the basket or container and not too tight together so such that a hand can slide in between them.
9) Process the load according to established internal procedures.
10) Handle pouches with care when removing from the sterilizer to prevent puncturing or tearing. Store pouches in an area protected from sunlight, water and other liquids.
11) Do not use wet pouches. In case of wet pouches, change the packaging and repeat the sterilization process.
12) To open the pouch, use thumb and index finger to hold plastic side of the pouch and thumb and index finger to pull back the paper side of the pouch. Always open the pouch towards the opening direction. Open the pouch slowly for a clean and aseptic presentation.

1.4.1 Restrictions in Use

PMSSteripack Tyvek sterilization reels and pouches are not designed to be used in dry heat and high temperature steam sterilization due to product's technical specifications. Packaging alternatives suitable for mentioned sterilization methods should be selected and used to provide optimum sterilization efficiency.

1.5 Product Size List

PMSSteripack Tyvek sterilization packaging is available in different types and dimensions to meet requirements of various medical devices to be packed and sterilized further.

Tyvek Sterilization FLAT Reels (TY)

Item Code	Dimension	Units/Box
TY0570	5cm x 70m	12
TY7570	7.5cm x 70m	8
TY1070	10cm x 70m	6
TY1570	15cm x 70m	4
TY2070	20cm x 70m	4
TY2570	25cm x 70m	2
TY3070	30cm x 70m	2
TY3570	35cm x 70m	2
TY4070	40cm x 70m	2
TY5070	50cm x 70m	2

Tyvek Sterilization FLAT Pouches (TP)

Item Code	Dimension	Units/Box
TP0520	5cm x 20cm	1.000
TP7520	7.5cm x 20cm	1.000
TP1028	10cm x 28cm	1.000
TP1530	15cm x 30cm	1.000
TP2040	20cm x 40cm	1.000
TP2545	25cm x 45cm	750

Additional sizes are available upon request. Please contact us at pms@pmsmedikal.com or through your responsible customer representative.

2. Tyvek Web

Tyvek manufactured by the company DuPont, is a rather unique material in the stable packaging materials classification. It is known for its outstanding strength, durability and tear resistance. Tyvek is used for low temperature hydrogen peroxide gas plasma sterilization methods and has also industrial use for ethylene oxide, formaldehyde and gamma sterilization.

Tyvek is made of 100% High Density Polyethylene (HPDE) filaments, flashspun and bonded using heat and pressure. The unique multiple layer structure with high porosity enables the penetration of sterilization gases into the package while preventing the ingress of microorganisms.

PMSSteripack Tyvek webs are available with Tyvek 2FS, Tyvek 1059B and Tyvek 1073B grades and are suitable for hydrogen peroxide gas plasma, ethylene oxide, formaldehyde and gamma sterilization methods. Standard PMSSteripack Tyvek sterilization packaging are constructed of 2FS Tyvek bottom web.

3. Chemical Indicator

PMSSteripack Tyvek sterilization reels and pouches are imprinted with a new and special for hydrogen peroxide plasma sterilization designed water based and non-toxic Class 1 chemical process indicator. The indicator is in compliance with ISO 11140-1 and fulfills the requirements of related standard.

The new H2O2 chemical process indicator offers a more stable and more accurate verification of successful completed sterilization cycles.

Chemical indicator for ethylene oxide and formaldehyde sterilization methods is available upon request.

3.1 Color Change of Chemical Indicators

PMS uses environmental friendly, water based, non-toxic indicator on Steripack tyvek reel and pouches. The indicator is tested under different printing conditions and accelerated aging studies are applied to the indicator printed on Tyvek web.

	PRE Sterilization	POST Sterilization
Color Change	**RED**	**BLUE**

3.2 Indicator Performance Testing

Chemical process indicators are defined by the international standard ISO 11140-1 and must fulfill the requirements at all time. PMSSteripack H2O2 chemical process indicator has been tested by an independent and accredited laboratory for performance requirements according ISO 11401-1.

3.2.1 H2O2 Indicator Performance Testing

The provided test samples with new H2O2 chemical process indicator have been processed in ISO compliant and calibrated low temperature hydrogen peroxide resistometer for pass and fail cycles per Table 6 of ISO 11140-1.

The results of the performance testing verify that the new H2O2 indicator used for PMSSteripack Tyvek sterilization packaging, performed as specified and met the requirements for a Class 1 hydrogen peroxide process indicator according ISO 11140-1.

- *Annex 12 | H2O2 Chemical Indicator Testing Report*

TESTING RESULTS

Test Environment	Test Time	Test Temperature	Gas Concentration mg/L	Test Result
Absence of Hydrogen Peroxide	45 min ± 5 min	50°C ± 0.5°C	None	Acceptable
Hydrogen Peroxide Test At:	7 s ± 1 s		2.3mg/L ± 0.4mg/L	Acceptable
	6 min ± 1 s			Acceptable

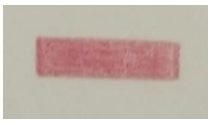
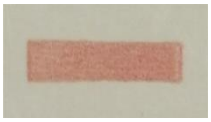
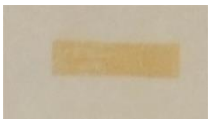
TABLE 2

3.3 Indicator Accelerated Ageing Study

PMSSteripack Tyvek sterilization packaging samples printed with new H2O2 plasma indicator have been accelerated aged by effect of high temperature (58°C) and humidity (%70Rh). The accelerated ageing periods have been simulated for 6, 12, 24 and 36 months and further exposed to hydrogen peroxide plasma sterilization (ASP, Sterrad 100S, Standard Cycle) and the required color change controlled.

The new H2O2 plasma process indicator of accelerated aged PMSSteripack Tyvek sterilization packaging met the expected color change performance after 6, 12, 24 and 36 months. All color changes are in acceptable limits.

- Annex 13 | New H2O2 İndicator Accelerated Ageing Test Report (6 month)
- Annex 14 | New H2O2 İndicator Accelerated Ageing Test Report (12 month)
- Annex 15 | New H2O2 İndicator Accelerated Ageing Test Report (24 month)
- Annex 16 | New H2O2 İndicator Accelerated Ageing Test Report (36 month)

Ageing Period	PRE Sterilization	POST Sterilization
6 month accelerated aged		
12 month accelerated aged		
24 month accelerated aged		
36 month accelerated aged		

4. Laminated PET/PE Film Web

The film web used for PMSSteripack Tyvek sterilization reels and pouches are constructed of transparent, reinforced multilayer (five) laminated PET/PE (Polyester/Polyethylene) film. PMS is one of three global manufacturers specialized for PE film extrusion for hydrogen peroxide plasma sterilization.

PMS developed a special PE film for hydrogen peroxide plasma sterilization providing a very wide sealing temperature range and reliable seal to uncoated Tyvek web and is ensuring a fibre-free aseptic presentation at any time.

PMS PE film offers a clean and uniform peel, can withstand sterilization procedures and its solvent-free production is more environmentally friendly.

PMS worked with DuPont in close collaboration during the development of the special film.

4.1 Properties of PET/PE Film Web

PMS uses specially developed laminated PET/PE film web for PMSSteripack branded Tyvek sterilization reels and pouches for hydrogen peroxide plasma sterilization. The film web is in compliance to requirements defined by European Standard EN 868-5 and all properties listed in below table are fulfilled at any time.

5. Final Product Testing

PMS first priority is to meet customer expectations by highest quality and standard conforming products. Implemented and applied quality control stages and in-house and/or external laboratory tests help us to ensure high product quality and sustainable production outcome. All final product of PMSSteripack Tyvek sterilization packaging are tested in compliance to ISO 11607-1, ISO 11140-1 and EN 868-5.

5.1 Final Product Specifications

Quality control testing is applied during various manufacturing stages and to the final product in determined frequencies. PMSSteripack Tyvek sterilization reels and pouches specific properties listed in below table are fulfilled at any time.

Properties	Unit	Value	Method	Frequency
Seal Width	mm	10±2 mm	EN 868-5 Annex D	For film and paper changes & every 2 hour.
Bubble Test	pcs	No leakage acc. Standard	ASTM F2096-04	Film and paper changed
Pinhole Determination	pcs	No pinhole acc. Standard	EN 868-5 Annex C	Each film roll
Dimension Control	cm	Refer to internal documentation	ASTM F2203-02	Film and paper changed
Leakage Test	pcs	No seal leaks acc. Standard	ASTM F 1929-98	Film and paper changed
Peel Direction	pcs	No fibers on the testing tape	EN 868-5 Annex E	Each printed roll
H2O2 Indicator Control	pcs	Color change from red to blue	Visual	Each printed roll
PET/PE film Bond Strength	N/15mm	>2,7 n/15 mm	ASTM F88	Each film roll
PET/PE film Delaminating	pcs	None Allowed	H2O2 Plasma Sterilization	Each film roll
Aseptic Presentation	pcs	No film or paper tear	Peel off / open slow	Each 2 hour of production
Bioburden Testing	pcs	Run and record	ISO 11737-1	At least every 3 month
Particles/Cleanliness	pcs	None Allowed	Visual	Each 2 hour of production
Microbial Barrier	pcs	Fulfill requirements of ASTM F1608	ASTM F 1608	Internal determined period
Wrinkles in Films or Seals	pcs	None Allowed	Visual	Each 2 hour of production
Jagged Edges	pcs	None Allowed	Visual	Each 2 hour of production
Stewed Printing	pcs	±2 mm	Visual	Each printed roll
Print Image	pcs	Artwork and readable	Visual	Each printed roll

5.2 Sterilization Efficacy Validation Test

Sterilization efficacy validation tests are used to determine the efficiency of medical sterilization packaging systems by processing them in a sterilizer validated to a sterility assurance level (SAL). Packaging are expected to meet the SAL at half cycle exposure time. On this report, Sterilization efficacy of PMSSteripack sterilization pouches were determined by the overkill method per AAMI and ISO guidelines. PMSSteripack pouches were processed in a Steris V-PRO 1 Plus Lumen sterilization cycle which is validated to a SAL of 10^{-6} *Geobacillus stearothermophilus* spores. The SAL was achieved by inoculating of these spores in the most difficult locations to sterilize and sealing them within PMSSteripack sterilization pouches. The pouches were processed at one-half the expected full cycle exposure time. Following exposure, the biological indicators were aseptically transferred to culture media and incubated as required. With this test method, sterilization was accomplished by demonstrating that a minimum 10^{-6} *Geobacillus stearothermophilus* spores were successfully killed in half cycle.

- Annex 17 | Sterilization Efficacy Test Report

5.3 Bioburden Properties

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. PMSSteripack Tyvek sterilization reels and pouches have been tested for bioburden after manufacturing process according ISO 11373-1 standard by an independent and accredited test laboratory every 3 months. PMSSteripack Tyvek sterilization packaging is produced in a controlled and clean environment and provide a safe and effective barrier against microorganism by no bacteria growth.

- Annex 18 | Bioburden Test Report TP7520

5.4 Microbial Barrier Properties

PMSSteripack Tyvek sterilization reels and pouches are proven and effective microbial barriers. Tyvek sterilization packaging have been tested for determining the microbial barrier properties following exposure to ASP, Sterrad 100NX at Standard Cycle by an external and accredited laboratory in the USA.

- Annex 19 | Microbial Aerosol Challenge Test Report

Tyvek sterilization packaging samples have been subjected to an aerosol of spores after exposure to Sterrad 100NX Standard Cycle sterilization process. Each packaging sample was loaded with stainless steel coupons, a biological indicator (BI) and a chemical indicator (CI). Following the exposure to microbial aerosol challenge, the BI's and stainless steel coupons were aseptically transferred to culture media and incubated as required.

Following the full incubation period, negative test samples were inoculated with spores and incubated for forty eight (48) hours per USP for growth promotion. The presence of growth verified the media could still support growth of a low number of challenge organism and that bacteriostatic substances did not inhibit growth.

- The test sample coupons demonstrated no growth following incubation of test samples.
- All positive controls were positive for growth
- All negative and environmental controls were negative for growth

PMSSteripack Tyvek sterilization packaging are an effective microbial barrier following ASP, Sterrad 100NX, Standard Cycle.

TEST RESULTS

Sample ID		Pouch # 1	Pouch # 2	Pouch # 3
LOT: 2213	1	N	N	N
	2	N	N	N
	3	N	N	N
	4	N	N	N
	5	N	N	N
	BI	N	N	N
Environmental Control – TSB 131209-1		N	N	N
Negative Control – TSB 131209-1		N	N	N
Positive Control –CycleSure BI		P	P	P
Negative Verification – LA12		P	P	P

TABLE 2

5.5 Cytotoxicity Testing

Cytotoxicity testing is crucial to ensure biocompatibility of medical devices. This involves extracting leachable materials from the device or components and analyzing the leachable extracts for potentially harmful chemicals or cytotoxicity. PMSSteripack Tyvek sterilization reels and pouches have been tested using MEM Elution Cytotoxicity Assay per USP and ISO methods after being processed in a Steris V-Pro 1 Plus lumen sterilization cycle by an external and accredited laboratory in the USA.

After being exposed to V-PRO 1 Plus Lumen Sterilization, L929 mammalian fibroblast cells samples were plated, incubated and extracted within MEM Elution fluid for 24±2 hours. Following incubation, cell culture medium was aspired and test samples were plated in triplicate with L929 cells and incubated for 48±2 hours. Following the full incubation period, the test samples met the USP and ISO 10993-5 requirements and PMSSteripack packaging proved its non-toxicity

PMSSteripack Tyvek sterilization packaging is non-toxic following Steris, V-PRO 1 Plus, lumen sterilization.

- Annex 20 | Cytotoxicity Test Report

5.6 Product Burst Test

Burst testing provides a quick means of assessing tendencies for a pouch to fail when it is exposed to a pressure differential. Pressure differentials may occur within a package during different situations, such as sterilization and transportation and it is important to ensure that the package can maintain integrity and therefore sterility throughout all reasonable circumstances. With this test, burst value of PMSSteripack Tyvek pouches is assessed per ASTM F1140.

- Annex 21 | Burst Test Report

5.6 Product Ageing Studies

PMS has applied product ageing studies for establishing the product shelf life of PMSSteripack Tyvek sterilization reels and pouches. Data obtained from these studies are based on conditions that simulate the effects of aging on the material and its properties. PMS product ageing studies consist of two parts; accelerated ageing and natural ageing for verification of shelf life under 'real-time' ageing conditions.

5.6.1 Accelerated Ageing

PMSSteripack Tyvek sterilization reels and pouches have a product shelf life of 3 (three) years under recommended storage and handling conditions. Accelerated ageing study valid for 3 years has been applied according ASTM F1980 to ensure highest quality and to determine the product shelf life. Accelerated aged products have been tested for their product properties internally at PMS laboratory.

5.6.2 Natural Ageing

Natural ageing is essential for verification of test results obtained after accelerated ageing. PMSSteripack Tyvek sterilization reels and pouches are stored under controlled and monitored environment and product physical property tests applied in a 6, 12, 18, 24 and 36 monthly period.

All data resulting from the testing have been evaluated and kept under record. The test results verify the shelf life of 3 (three) years for PMSSteripack Tyvek sterilization reels and pouches under recommended storage conditions.

6. Product Packaging

The product packaging of PMSSteripack Tyvek sterilization reels and pouches consists of three packaging types; the inner packaging, the outer packaging and the transport packaging. Each packaging is done after the final product quality control by trained personnel and by use of proper selected materials to ensure protection from dust and moisture during transportation and storage.

The inner packaging of Tyvek sterilization pouches is done in bundles of 250 pieces and wrapped with PP film. Tyvek Sterilization reels of 70 meter lengths are placed in PE bags single or in groups depending on the reel width.

For outer packaging of PMS products, double wall corrugated cardboard boxes as shipping cartons are used. The double wall corrugated structure provides higher protection against any kind of damages during transportation and handling.

The transport packaging as the final stage prior shipment, is done by use of 4way wooden and heat treated (according ISPM-15) pallets. Proper placed shipping cartons are wrapped with PP film for protection against dust and moisture and secured with edge protections and 12m wide PET belts.

6.1 LOT Number

Each PMSSteripack Tyvek sterilization reel and pouch is provided with a LOT number printed on the Tyvek bottom web. The LOT number allows the traceability of the product during the manufacturing process.

The LOT number is coded as following;

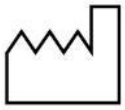
LOT WWYY

- **WW** = Week of the year
- **YY** = Year of manufacturing

6.2 Expiry Date / Shelf Life

The shelf life of PMSSteripack Tyvek sterilization reels and pouches is 3 (three) years after manufacture date under recommended storage and handling conditions.

The product must be used within 3 years from date of manufacture. The expiry date, as well as the manufacture date are printed on the product traceability labels and the shipping carton label.



Manufacture Date Symbol
dd.MM.yy

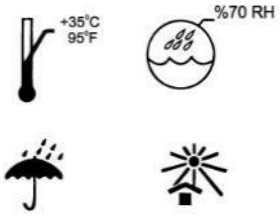
Expiry Date Symbol
dd.MM.yy

6.3 Storage Conditions

PMSSteripack Tyvek sterilization reels and pouches need to be stored under following recommended storage conditions to ensure optimum product quality, microbial properties and expiry date.

Storage conditions are printed on each shipping carton labels and are also available at product related instructions for use.

- Stored in original packaging
- Stored under controlled temperature (max. 35°C)
- Stored under controlled humidity (max. %70 Relative Humidity)
- Stored protected from direct sunlight, moisture and excessive airflow



6.4 Product Traceability Label

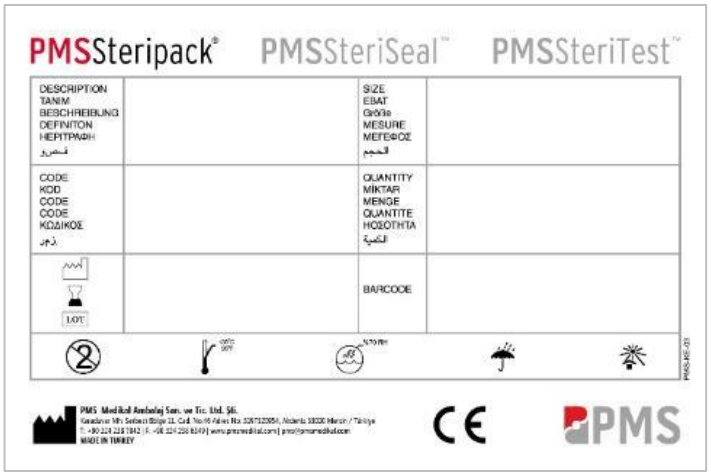
Each Tyvek sterilization reel and pouch bundle is attached with a label including important product and manufacturing information. These labels are essential for product traceability and must be keep safe in case of any product related subjects. Each product traceability label contains following details;

- Product Item Code (Ref.)
- Lot Number
- Manufacture Date
- Expiry Date
- Machine No
- Roll / Pouch Bundle No
- Product specific barcode

6.5 Shipping Carton Label

Each shipping carton is attached with a label including essential product information and traceability data. Each label contains following details;

- Brand
- Product description
- Product Dimension
- Product Item Code
- Quantity
- Manufacture Date
- Expiry Date
- Lot Number
- Recommended storage conditions
- Product Barcode
- Manufacturer contact details
- CE Mark



Annex 1 | ISO 9001 Certification

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SAN. VE TİC. A.Ş.
Karaduvar Mah. Serbest Bölge 11. Cadde No:46 33020
Mersin Serbest Bölgesi Akdeniz - Mersin / TURKEY

has been approved by Lloyd's Register Quality Assurance to the following Quality Management System Standards:

ISO 9001:2008

The Quality Management System is applicable to:

Production, Marketing and Sales of Sterilisation Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes, Bowie-Dick Test Packs, Sealing Machines and Autoclavable Biohazard Bags

Approval
Certificate No: IST6008159/A

Original Approval: 22 November 2009
Current Certificate: 05 November 2015
Certificate Expiry: 14 September 2018

Issued by: Lloyd's Register Gözetim Ltd Sti.
For and on behalf of Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register Gözetim Ltd. Sti, Ataturk Cd, SitkiBey Plaza, No 82, K 3, D 12, Kozyatagi, Istanbul / TURKIYE
For and on behalf of LRQA Ltd, 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001
Macro Revision 15

Annex 2 | ISO 13485 Certification

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

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PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SAN. VE TİC. A.Ş.
Karaduvar Mah. Serbest Bölge 11. Cadde No:46 33020
Mersin Serbest Bölgesi Akdeniz - Mersin / TURKEY

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003
The Quality Management System is applicable to:

Design, Development, Production, Marketing and Sales of Sterilisation Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes, Bowie-Dick Test packs and Autoclavable Biohazard Bags (Class 1)

Approval
Certificate No: IST6008159/B

Original Approval: 22 November 2009
Current Certificate: 05 November 2015
Certificate Expiry: 14 September 2018

Issued by: Lloyd's Register Gözetim Ltd Sti
For and on behalf Of Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register Gözetim Ltd. Sti, Ataturk Cd, SitkiBey Plaza, No 82, K 3, D 12, Kozyatagi, Istanbul / TURKIYE
For and on behalf of LRQA Ltd, 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001
Macro Revision 15

Annex 3 | CE Declaration of Conformity

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SAN. VE TİC. A.Ş
Karaduvar Mah. Serbest Bölge 11. Cadde
No: 46, Akdeniz, PK: 33020
MERSİN - TURKEY
TEL : (324) 238 70 42 (pbx)
FAX : (324) 238 65 49
E Mail : pms@pmsmedikal.com
www.pmsmedikal.com

CE DECLARATION OF CONFORMITY

EU Directives covered by this Declaration

93/42/EEC MEDICAL DEVICE DIRECTIVE / 2007/47/EC

The Products Covered by this Declaration

Tyvek Sterilization Reel (Flat)
Tyvek Sterilization Pouch (Flat)

The Basis on which Conformity is being Declared

The product identified above complies with the requirements of the Medical Device Directory and its annexes above by meeting the following standard: *EN 868-5, ISO 11140-1 and ISO 11607*

The product is defined as Class 1 product and Declaration of Conformity is issued as per Annex VII of 93/42/EEC MDD.

The technical documentation required to demonstrate that the product meets the requirements of the Medical Device Directive has been compiled by the signatory below and is available for inspection by the relevant enforcement authorities.

The CE mark was first applied in May 2000

The products described above comply with the essential requirements of the directives specified.

Authority: Taner ERSEN
Date : February 2018

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SANAYİ VE TİCARET A.Ş.

ATTENTION!
The attention of the specifier, purchaser, installer, or user is drawn to special measures and limitations to use which must be observed when the product is taken into service to maintain compliance with the above directives. Details of these special methtods and limations to use are available on request.

Annex 4 | FDA 510K Summary Report

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 18, 2016

PMS TIBBI CIHAZLAR TEKNOLOJISI SANAYI VE TICARET ANONIM ŞIRKETI
Derya Dikici, Ph.D.
Business Development Manager
Karaduvar Mahallesi, Serbest Bolge 11. Cadde No:46
Mersin Serbest Bolgesi, 33020, Akdeniz/MERSIN/TURKEY

Re: K160595
Trade/Device Name: PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: October 10, 2016
Received: October 19, 2016

Dear Derya Dikici:

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. 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 and Part 809); medical device reporting (reporting of

Page 2 - Derya Dikici, Ph.D.

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Annex 5 | TSE EN 868-5 Certification

TÜRK STANDARDLARI ENSTİTÜSÜ
TÜRK STANDARDLARINA UYGUNLUK BELGESİ
TURKISH STANDARDS INSTITUTION
CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı — Description of the Mark
TSE veya/or TSE veya/or TSE

BELGE NUMARASI *REFERENCE NUMBER OF LICENCE*	038154-TSE-01/01
BELGENİN İLK VERİLİŞ TARİHİ *DATE OF FIRST ISSUE OF LICENCE*	26.10.2003
BELGENİN SON GEÇERLİLİK TARİHİ *LICENCE VALID UNTIL*	27.10.2018
BELGE SAHİBİ KURULUŞUN ADI *NAME OF THE LICENCE HOLDER*	PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SANAYİ VE TİCARET ANONİM ŞİRKETİ
BELGE SAHİBİ KURULUŞUN ADRESİ *ADRESS OF THE LICENCE HOLDER*	KARADUVAR SB MAH. SERBEST BÖLGE 11. CAD. NO:46 AKDENİZ MERSİN/TÜRKİYE
ÜRETİM YERİ ADI *NAME OF THE MANUFACTURING PLACE*	PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SANAYİ VE TİCARET ANONİM ŞİRKETİ
ÜRETİM YERİ ADRESİ *ADRESS OF THE MANUFACTURING PLACE*	KARADUVAR MAH. SERBEST BÖLGE 11. CADDE NO:46 AKDENİZ MERSİN / TÜRKİYE
İPTAL EDİLEN BELGE NUMARASI (Varsa) *INDICATION OF SUPERSEDED LICENCE (if any)*	14.0.30.4.01.00/TSE-15688
TESCİLLİ TİCARİ MARKASI *REGISTERED TRADE MARK*	PMSSteripack
İLGİLİ TÜRK STANDARDI *RELATED TURKISH STANDARD*	TS EN 868-5 / Nihai olarak sterilize edilen tıbbi cihazlar için ambalajlama malzemeleri - Bölüm 5: Gözenekli malzemelerden ve plastik filmden yapılan kendinden kapatılabilir poşetler ve rulolar - Özellikler ve deney metotları / 27.12.2012

BELGE KAPSAMI
SCOPE OF LICENCE

STERİLİZASYON RULOSU

27.10/2017
KÜRŞAT ONUR
TSE ADANA BELGELENDİRME MÜDÜRÜ V

*Bu belge, belgelendirilen ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.
*Bu belge hiç bir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
*TSE ADANA BELGELENDİRME MÜDÜRLÜĞÜ * Adres: Çınarlı Mah. Turhan Cemal Beriker Bulvarı Gizerler İşhanı No:46 Kat:7 / 16-17 Seyhan / ADANA * Tel: 0 322 458 19 40-41* Faks: 0322-4588243
*TSE BELGELENDİRME MERKEZİ BAŞKANLIĞI; Adres: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA – Tel: 0 312 416 64 81 / 416 64 27, Faks: 0 312 416 66 17
e-posta : bmb@tse.org.tr , web : www.tse.org.tr

https://evrakkontrol.tse.org.tr/BelgeDogrulama.aspx?p=ufogeiem adresinden belgenin doğruluğunu ve geçerliliğini sorgulayınız.

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Annex 6 | Technical Data Sheet Tyvek Sterilization Reel (2FS)

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (2 FS)

TECHNICAL DATA SHEET

PRODUCT CODE : **TY**

RELATED STANDARDS : PMSSteripack Tyvek Reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Reels meet the requirements of 93/42/EEC Medical Device Directive regulations with the amendment of 2007/47/EC.

INTENDED USE : The Tyvek Reels are used to sterilze Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack Reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek Reels are used for ethylene oxide, gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,7
	BASIC WEIGHT	g/m²	60
	POROSITY	sec/100 cc	22
	OPACITY	%	94
	THICKNESS	µm	155
	SPENCER PUNCTURE	J/m	5254
	MULLEN BURST	kPa	925
	HYDROSTATIC HEAD	cm H2O	145
	ELMENDORF TEAR, CD	mN	3694
	ELMENDORF TEAR, MD	mN	2803
	TENSILE STRENGTH,CD	N/2.54 cm	157
	TENSILE STRENGTH,MD	N/2.54 cm	156
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

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pms@pmsmedikal.com

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (2 FS)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	64 ± 5
				PE	50 ± 5
				PET	12 ± 2
	THERMAL SEAL	°C	ASTM F 88	110 ± 5	
	TENSILE	N/15 mm MD	ASTM D 882-12	min. 26	
		CD		min. 26	
	TEAR	mN MD	ASTM D 1922	min. 90	
		CD		min. 90	
	HAZE	%	ASTM D 1003	max. 17	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
REEL	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 0,75
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Required dimensions	
	LEAKAGE TEST		ASTM F 1929-12	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

PACKAGING : PMSSteripack TYVEK reels are packaged as below.

Product Code	Pieces in Inner Packaging	Pieces in carton
05 cm	6	12
7,5 cm	4	8
10 cm	3	6
15 cm	2	4
20 cm	2	4
25 cm	1	2
30 cm	1	2
35 cm	1	2
40 cm	1	2

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Rev.02

Annex 7 | Technical Data Sheet Tyvek Sterilization Pouch (2FS)

TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (2 FS)

TECHNICAL DATA SHEET

PRODUCT CODE : **TP**

RELATED STANDARDS : PMSSteripack Tyvek Pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations with the amendment of 2007/47/EC.

INTENDED USE : The Tyvek Pouches are used to sterilze Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack Pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek Pouches are used for ethylene oxide, gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,7
	BASIC WEIGHT	g/m²	60
	POROSITY	sec/100 cc	22
	OPACITY	%	94
	THICKNESS	µm	155
	SPENCER PUNCTURE	J/m	5254
	MULLEN BURST	kPa	925
	HYDROSTATIC HEAD	cm H2O	145
	ELMENDORF TEAR, CD	mN	3694
	ELMENDORF TEAR, MD	mN	2803
	TENSILE STRENGTH,CD	N/2.54 cm	157
	TENSILE STRENGTH,MD	N/2.54 cm	156
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

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TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (2 FS)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	64 ± 5
				PE	50 ± 5
				PET	12 ± 2
	THERMAL SEAL	°C	ASTM F 88	110 ± 5	
	TENSILE	N/15 mm MD	ASTM D 882-12	min. 26	
		CD		min. 26	
	TEAR	mN MD	ASTM D 1922	min. 90	
		CD		min. 90	
	HAZE	%	ASTM D 1003	max. 17	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 0,75
		Top Seal (N/15 mm)		4,0 ± 0,5	5,0 ± 0,5
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Required dimensions	
	LEAKAGE TEST		ASTM F 1929-12	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

PACKAGING : PMSSteripack TYVEK reels are packaged as below.

Product Code	Pieces in Inner Packaging	Pieces in carton
05 cm	6	12
7,5 cm	4	8
10 cm	3	6
15 cm	2	4
20 cm	2	4
25 cm	1	2
30 cm	1	2
35 cm	1	2
40 cm	1	2

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Rev.02

Annex 8 | Technical Data Sheet Tyvek Sterilization Reel (1059B)

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (1059B)

TECHNICAL DATA SHEET

PRODUCT CODE : **TY**

RELATED STANDARDS : PMSSteripack Tyvek reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek reels meet the requirements of 93/42/EEC Medical Device Directive regulations with the amendment of 2007/47/EC and Class 2 according to US FDA.

INTENDED USE : The Tyvek reels are used to sterilze Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek reels are used for gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,2
	BASIC WEIGHT	g/m²	64,4
	POROSITY	sec/100 cc	22
	OPACITY	%	91
	THICKNESS	µm	165
	SPENCER PUNCTURE	J/m2	6195
	MULLEN BURST	kPa	1055
	HYDROSTATIC HEAD	cm H2O	142
	ELMENDORF TEAR, CD	mN	3203
	ELMENDORF TEAR, MD	mN	2980
	TENSILE STRENGTH,CD	N/2.54 cm	174
	TENSILE STRENGTH,MD	N/2.54 cm	163
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

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TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (1059B)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	min. 55
				PE	50 ± 5
				PET	12 ± 2
	THERMAL SEAL	°C	ASTM F 88	110 ± 5	
	TENSILE	N/15 mm MD	ASTM D 882-12	min. 26	
		CD		min. 26	
	TEAR	mN MD	ASTM D 1922	min. 90	
		CD		min. 90	
	HAZE	%	ASTM D 1003	max. 17	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		min. 1.5	min. 1.5
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Required dimensions	
	LEAKAGE TEST		ASTM F 1929-12	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	**Red**	**Blue**

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Rev.02

Annex 9 | Technical Data Sheet Tyvek Sterilization Pouch (1059B)

TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (1059B)

TECHNICAL DATA SHEET

PRODUCT CODE : **TP**

RELATED STANDARDS : PMSSteripack Tyvek Pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations with the amendment of 2007/47/EC and Class 2 according to US FDA.

INTENDED USE : The Tyvek Pouches are used to sterilze Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack Pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek Pouches are used for gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,2
	BASIC WEIGHT	g/m²	64,4
	POROSITY	sec/100 cc	22
	OPACITY	%	91
	THICKNESS	µm	165
	SPENCER PUNCTURE	J/m2	6195
	MULLEN BURST	kPa	1055
	HYDROSTATIC HEAD	cm H2O	142
	ELMENDORF TEAR, CD	mN	3203
	ELMENDORF TEAR, MD	mN	2980
	TENSILE STRENGTH,CD	N/2.54 cm	174
	TENSILE STRENGTH,MD	N/2.54 cm	163
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

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TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (1059B)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	min. 55
				PE	50 ± 5
				PET	12 ± 2
	THERMAL SEAL	°C	ASTM F 88	110 ± 5	
	TENSILE	N/15 mm MD	ASTM D 882-12	min. 26	
		CD		min. 26	
	TEAR	mN MD	ASTM D 1922	min. 90	
		CD		min. 90	
	HAZE	%	ASTM D 1003	max. 17	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		min. 1.5	min. 1.5
		Top Seal (N/15 mm)		min. 1.5	min. 1.5
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Required dimensions	
	LEAKAGE TEST		ASTM F 1929-12	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

PMSSteripack®

Annex 10 | Technical Data Sheet Tyvek Sterilization Reel (1073B)

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (1073B)

TECHNICAL DATA SHEET

PRODUCT CODE : **TY**

RELATED STANDARDS : PMSSteripack Tyvek Reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Reels meet the requirements of 93/42/EEC Medical Device Directive regulations

INTENDED USE : The Tyvek Reels are used to sterilze Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack Reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek Reels are used for ethylene oxide, formaldehyde,gas plazma (VH2O2) sterlization.The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,31
	BASIC WEIGHT	g/m²	74,6
	POROSITY	sec	22
	OPACITY	%	92,4
	THICKNESS	µm	185
	SPENCER PUNCTURE	J/m	7355
	MULLEN BURST	kPa	1227
	HYDROSTATIC HEAD	cm H2O	150
	ELMENDORF TEAR, CD	mN	3514
	ELMENDORF TEAR, MD	mN	3425
	TENSILE STRENGTH,CD	N/2.54 cm	208
	TENSILE STRENGTH,MD	N/2.54 cm	193
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

PMSSteripack®

PMS Tıbbi Cihazlar Teknolojisi San. ve Tic. A.Ş
pms@pmsmedikal.com

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL (1073)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	65 ± 5
				PE	50 ± 5
				PET	12 ± 2
	COF	F/M	ASTM F 1894	0,30-0,35	
		F/F		0,35-0,40	
	THERMAL SEAL	°C	ASTM F 88	110 ± 5	
	TEAR	mN MD	ASTM D 1922	90 min.	
		CD		90 min.	
	GLOSS	%	ASTM D 2457	60 ± 5	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPESIFICATION :

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
REEL	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N /15 mm)		3,0 ± 0,5	4,0 ± 0,75
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Desired dimensions	
	LEAKAGE TEST		ASTM F 1929-98	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

PACKAGING : PMSSteripack TYVEK reels are packaged as below.

Product Code	Pieces in Inner Packaging	Pieces in carton
05 cm	6	12
7,5 cm	4	8
10 cm	3	6
15 cm	2	4
20 cm	2	4
25 cm	1	2
30 cm	1	2
35 cm	1	2
40 cm	1	2

PMS

PMSSteripack®

PMS Tıbbi Cihazlar Teknolojisi San. ve Tic. A.Ş
pms@pmsmedikal.com

Rev.02

Annex 11 | Technical Data Sheet Tyvek Sterilization Pouch (1073B)

TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (1073B)

TECHNICAL DATA SHEET

PRODUCT CODE : **TP**

RELATED STANDARDS : PMSSteripack Tyvek pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations

INTENDED USE : The Tyvek Pouches are used to sterilze temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.

OPERATION CONDITIONS : PMSSteripack Tyvek pouches are used for ethylene oxide, formaldehyde,gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNITS	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,31
	BASIC WEIGHT	g/m²	74,6
	POROSITY	sec	22
	OPACITY	%	92,4
	THICKNESS	µm	185
	SPENCER PUNCTURE	J/m	7355
	MULLEN BURST	kPa	1227
	HYDROSTATIC HEAD	cm H2O	150
	ELMENDORF TEAR, CD	mN	3514
	ELMENDORF TEAR, MD	mN	3425
	TENSILE STRENGTH,CD	N/2.54 cm	208
	TENSILE STRENGTH,MD	N/2.54 cm	193
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

PMSSteripack®

PMS Tıbbi Cihazlar Teknolojisi San. ve Tic. A.Ş
pms@pmsmedikal.com

TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (1073)

	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	65 ± 5
				PE	50 ± 5
				PET	12 ± 2
	COF	F/M	ASTM F 1894	0,30-0,35	
		M/M		0,35-0,40	
	THERMAL SEAL	C°	ASTM F 88	110 ± 5	
	TEAR	mN MD	ASTM D 1922	90 min.	
		CD		90 min.	
	GLOSS	%	ASTM D 2457	60 ± 5	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATION :

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N /15 mm)		3,0 ± 0,5	4,0 ± 0,75
		Top Seal (N /15 mm)		4,0 ± 0,5	5,0 ± 0,5
	BUBBLE TEST		ASTM F 2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Desired dimensions	
	LEAKAGE TEST		ASTM F 1929-98	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

PACKAGING : PMSSteripack TYVEK pouches are packaged 250 pieces in each laminated film and each 1000 pouch are packaged in cartons.

PMSSteripack®

PMS Tıbbi Cihazlar Teknolojisi San. ve Tic. A.Ş
pms@pmsmedikal.com

Rev.02

Annex 12 | H2O2 Chemical Indicator Test Report

HIGHPOWER
Validation Testing & Lab Services

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125 Highpower Road • Rochester NY, 14623 USA

FINAL REPORT

Confidential & Proprietary

Study No. 1410-597

ISO 11140 VAPORIZED HYDROGEN PEROXIDE (VHP) CHEMICAL INDICATOR TESTING OF THE PMS TIP TYVEK® (TP) STERILIZATION POUCHES

Prepared for:

PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI
Mersin Tarsus Organize
Sanayi Bolgesi 12.Cad. No:2
Huzurkent/Mersin
TURKEY

Prepared by:

HIGHPOWER Validation Testing & Lab Services
125 Highpower Road
Rochester, NY 14623

Approved by:

Donald Tumminelli
Manager, Validation & Testing Services
HIGHPOWER Validation Testing & Lab Services

3/12/15
Date

FINAL REPORT
HIGHPOWER Study No. 1410-597
PMS TIP Tyvek® (TP) Sterilization Pouches
Vaporized Hydrogen Peroxide (VHP) Chemical Indicator Testing

Study No.:	1410-597
Sponsor:	PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI Mersin Tarsus Organize Sanayi Bolgesi 12.Cad. No:2 Huzurkent/Mersin TURKEY
Study Director:	Don Tumminelli Manager, Validation & Lab Services
Study Personnel:	Alex Belik – Senior Microbiology Technician
Report Prepared By:	Alex Belik – Senior Microbiology Technician
Test Objective:	To process the PMS TIP Tyvek® (TP) Sterilization Pouches to the performance requirements of ISO 11140-1.
Test Sample:	PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1

References:

1. United States Pharmacopeia. Current Edition.
2. ANSI/AAMI/ISO 11140-1:2005, Sterilization of health care products—Chemical indicators—Part 1: General requirements

FINAL REPORT
HIGHPOWER Study No. 1410-597
PMS TIP Tyvek® (TP) Sterilization Pouches
Vaporized Hydrogen Peroxide (VHP) Chemical Indicator Testing

1.0 INTRODUCTION:

This report details the methods used in evaluating the chemical indicators printed on the PMS TIP Tyvek® (TP) Sterilization Pouches when tested in accordance with ANSI/AAMI/ISO 11140-1:2005.

2.0 JUSTIFICATION:

Chemical indicators are a necessary visual component utilized by end-users to identify devices or products that have been subjected to a sterilization process. It is important that these chemical indicators comply with the requirements of ISO 11140-1 in the sterilizers and temperatures in which they will be used. Testing was not performed at 27°C, as the pouch manufacturer is not recommending their pouches for use in sterilization cycles running at this temperature.

3.0 EQUIPMENT & MATERIALS:

3.1 PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1
3.2 Vaporized Hydrogen Peroxide Resistometer compliant to ANSI/AAMI/ISO 18472:2006/(R)2010

4.0 VAPORIZED HYDROGEN PEROXIDE TESTING MATRIX: ISO 11140-1 TABLE 6

Test Environment	Test Time	Test Temperature	Gas Concentration mg/L	No change or a change that is markedly different from the visible change as specified by the manufacturer	Visible change as specified by the manufacturer
Absence of Hydrogen Peroxide	45 min ± 5 min	50°C ± 0.5°C	None	Acceptable Result	Unacceptable Result
	45 min ± 5 min	*27°C ± 0.5°C			
Hydrogen Peroxide Test At:	7s ± 1 s	50°C ± 0.5°C	2.3mg/L ± 0.4mg/L	Acceptable Result	Unacceptable Result
	10s ± 1s	*27°C ± 0.5°C	2.3mg/L ± 0.4mg/L		
Hydrogen Peroxide Test At:	6 min ± 1 s	50°C ± 0.5°C	2.3mg/L ± 0.4mg/L	Unacceptable Result	Acceptable Result
	10 min ± 1s	*27°C ± 0.5°C			

***NOTE:** No testing was performed at this temperature.

5.0 PROCEDURE:

5.1 Five (5) each of the PMS TIP Tyvek® (TP) Sterilization Pouches were obtained: See Bill of Materials, Table 1.
5.2 The samples were processed according to the 50°C Test Environments listed in Table 6 of ANSI/AAMI/ISO 11140-1:2005.
5.3 All results were recorded and photo documented. See Tables 2 and 3.
5.4 Samples were sent back to sponsor.

FINAL REPORT
HIGHPOWER Study No. 1410-597
PMS TIP Tyvek® (TP) Sterilization Pouches
Vaporized Hydrogen Peroxide (VHP) Chemical Indicator Testing

6.0 RESULTS:

The chemical indicator on the PMS TIP Tyvek® (TP) Sterilization Pouch samples ran in the pass cycles reached their signal color of Blue.

The chemical indicator on the PMS TIP Tyvek® (TP) Sterilization Pouch samples ran in the failure cycles did not reach their signal color and were markedly different from indicators run in full cycles.

7.0 DISCUSSION:

One deviation from the protocol was requested by the sponsor. This request was for all references to the company name as PMS Medikal to be changed to PMS TIP, and to also update the company address. These updates have been made and are reflected in this Final Report.

8.0 CONCLUSION:

Results of testing verify that the PMS TIP Tyvek® (TP) Sterilization Pouches conform to the ANSI/AAMI/ISO 11140-1 performance requirements for class 1 vaporized hydrogen peroxide process indicators when tested at 50°C.

BILL OF MATERIALS
PMS TIPS TYVEK® (TP) STERILIZATION POUCHES

Pouch Size	Product Code	Lot #	Quantity*	Status
50 x 200 mm	TP 0520	3611	5	Aged
150 x 300 mm	TP 1530	3711	5	Aged
350 x 600 mm	TP 3560	3811	5	Aged
50 x 200 mm	TP 0520	4214	5	Unaged
150 x 300 mm	TP 1530	3214	5	Unaged
350 x 600 mm	TP 3560	4514	5	Unaged

TABLE 1

*Quantities are per cycle

TESTING RESULTS

Test Environment	Test Time	Test Temperature	Gas Concentration mg/L	Test Result
Absence of Hydrogen Peroxide	45 min ± 5 min	50°C ± 0.5°C	None	Acceptable
Hydrogen Peroxide Test At:	7 s ± 1 s		2.3mg/L ± 0.4mg/L	Acceptable
	6 min ± 1 s			Acceptable

TABLE 2

FINAL REPORT
HIGHPOWER Study No. 1410-597
PMS TIP Tyvek® (TP) Sterilization Pouches
Vaporized Hydrogen Peroxide (VHP) Chemical Indicator Testing

PHOTOS OF PASS, FAILURE, AND UNPROCESSED SAMPLES

Sample ID	2.3 mg/L H_2O_2 50°C 6 minutes	2.3 mg/L H_2O_2 50°C 7 seconds	Absence of H_2O_2	Unprocessed
Product Code: TP 0520 Lot #: 3611				
Product Code: TP 1530 Lot #: 3711				
Product Code: TP 3560 Lot #: 3811				
Product Code: TP 0520 Lot #: 4214				
Product Code: TP 1530 Lot #: 3214				
Product Code: TP 3560 Lot #: 4514				

TABLE 3

Annex 13 | H2O2 Indicator Accelerated Test Report (6 months)

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

İstiklal Mahallesi Atatürk Cad. No:21 Esenyurt İstanbul
Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep no:TLP-13-2600 Request no	**STABİLİTE İZLEME RAPORU** STABILITY MONITORING REPORT	M13-1117 13.01.2014
Teklif no:TLF-13-690 Tender no		
Kabul Tarihi:19.12.2013 Receiving Date		
Test başlangıç Tarihi:19.12.2013 Test Initiation Date:		
Test Bitiş Tarihi:06.01.2014 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

PMS MEDİKAL AMB.SAN.TİC.LTD.ŞTİ.
DR.AYHAN AYBAR CAD.6.SOK.NO.11 SERBEST BÖLGE MERSİN

❖ **TEST AMACI /** TEST TARGET

Testin hedefi, numunelerin yüksek sıcaklık ve nem etkisiyle hızlandırılmış olarak yaşlandırılmasını sağlamaktır
The target of this test is ensuring the samples accelerated aging by the effect of high temperature and humidity.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Cihaz No/Equipment No:LF020
Sıcaklık/Temperature: 58 ° C
Nem/Humidity:% 70
Müşteri tarafından beyan edilen depolama sıcaklığı:23 ° C
Warehousing temperature that is declared by customer:
Süre/Time:16 gün = 2 hafta=6 ay

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Tyvek Sample 2 17.06.2013
N13-4444

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not Used

NA: Uygulanamaz/Not applicable 1 / 2 10.06.13 / 270118-F39–02

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

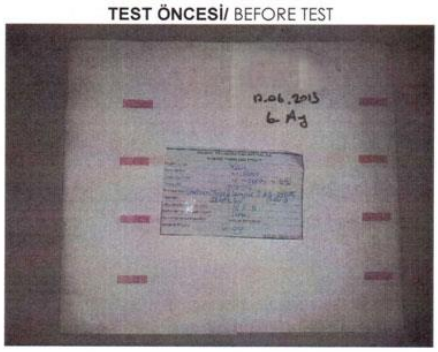
M13-1117
13.01.2014

❖ **ÖLÇÜM ANALİZ SONUÇLARI/** TEST RESULTS

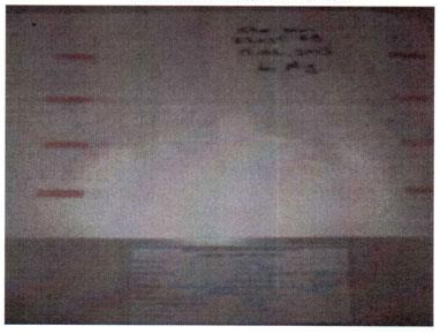
PARAMETRE	SONUÇ
Ambalaj Görünümü/ Packing View	UYGUN
Ürün Görünümü/ Product View	UYGUN

❖ **NUMUNE RESİMLERİ/** SAMPLE PHOTOS

TEST ÖNCESİ/ BEFORE TEST



TEST SONRASI/ AFTER TEST



❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Aysel YILDIRIM KİMYAGER		13.01.14
Laboratuar Onayı / Laboratory Approval:	Aysel YILDIRIM KİMYAGER		13.01.14
Kalite onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER		13.01.14
Mühür/Seal:	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report
Bu rapor Bıçakcılar Laboratuarının yazılı onayı olmadan kısmen kopyalanamaz.
İmzasız ve mühürsüz raporlar geçersizdir.
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Testing reports without signature and seal are not valid

NA: Uygulanamaz/Not applicable 2 / 2 10.06.13 / 270118-F39–02

Annex 14 | H2O2 Indicator Accelerated Test Report (12 months)

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep no:TLP-13-2600 Request no	**STABİLİTE İZLEME RAPORU** STABILITY MONITORING REPORT	M13-1118 23.01.2014
Teklif no:TLF-13-690 Tender no		
Kabul Tarihi:19.12.2013 Receiving Date		
Test başlangıç Tarihi:19.12.2013 Test Initiation Date:		
Test Bitiş Tarihi:20.01.2014 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

PMS MEDİKAL AMB.SAN.TİC.LTD.ŞTİ.
KARADUVAR MAH. SERBEST BÖLGE 11. CADDE NO: 46, AKDENIZ, 33020 MERSIN

❖ **TEST AMACI /** TEST TARGET

Testin hedefi, numunelerin yüksek sıcaklık ve nem etkisiyle hızlandırılmış olarak yaşlandırılmasını sağlamaktır
The target of this test is ensuring the samples accelerated aging by the effect of high temperature and humidity.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Cihaz No/Equipment No:LF020
Sıcaklık/Temperature: 58 ° C
Nem/Humidity:% 70
Müşteri tarafından beyan edilen.depolama sıcaklığı:23 ° C
Warehousing temperature that is declared by customer:
Süre/Time:32 gün = 5 hafta=1 yıl

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

[redacted] Tyvek Sample2 [redacted] -17.06.2013
N13-4445

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not Used

NA: Uygulanamaz/Not applicable 1 / 2 10.06.13 / 270118-F39-02

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

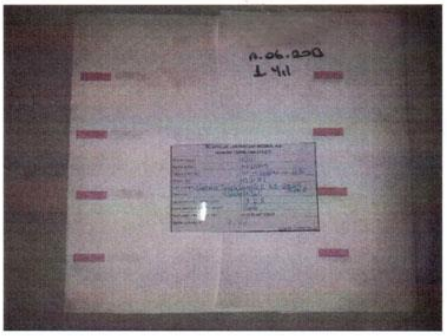
M13-1118
23.01.2014

❖ **ÖLÇÜM ANALİZ SONUÇLARI/** TEST RESULTS

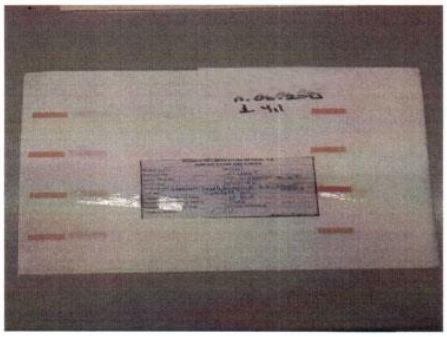
PARAMETRE	SONUÇ
Ambalaj Görünümü/ Packing View	UYGUN
Ürün Görünümü/ Product View	UYGUN

❖ **NUMUNE RESİMLERİ/** SAMPLE PHOTOS

TEST ÖNCESİ/ BEFORE TEST



TEST SONRASI/ AFTER TEST



❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Aysel YILDIRIM KİMYAGER	.....	23.01.14
Laboratuar Onayı / Laboratory Approval:	Aysel YILDIRIM KİMYAGER	.....	23.01.14
Kalite onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER	.....	23.01.14
Mühür/Seal:	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report
Bu rapor Bıçakcılar Laboratuarının yazılı onayı olmadan kısmen kopyalanamaz.
İmzasız ve mühürsüz raporlar geçersizdir.
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Testing reports without signature and seal are not valid

NA: Uygulanamaz/Not applicable 2 / 2 10.06.13 / 270118-F39–02

Annex 15 | H2O2 Indicator Accelerated Test Report (24 months)

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http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep no:TLP-13-2600 Request no	**STABİLİTE İZLEME RAPORU** STABILITY MONITORING REPORT	M13-1119 24.02.2014
Teklif no:TLF-13-690 Tender no		
Kabul Tarihi:19.12.2013 Receiving Date		
Test başlangıç Tarihi:19.12.2013 Test Initiation Date:		
Test Bitiş Tarihi:21.02.2014 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

PMS MEDİKAL AMB.SAN.TİC.LTD.ŞTİ.
KARADUVAR MAH. SERBEST BÖLGE 11. CADDE NO: 46, AKDENIZ, 33020 MERSIN

❖ **TEST AMACI /** TEST TARGET

Testin hedefi, numunelerin yüksek sıcaklık ve nem etkisiyle hızlandırılmış olarak yaşlandırılmasını sağlamaktır
The target of this test is ensuring the samples accelerated aging by the effect of high temperature and humidity.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Cihaz No/Equipment No:LF020
Sıcaklık/Temperature: 58 ° C
Nem/Humidity:% 70
Müşteri tarafından beyan edilen depolama sıcaklığı:23 ° C
Warehousing temperature that is declared by customer:
Süre/Time:65 gün = 9 hafta=2 yıl

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Tyvek Sample2 -17.06.2013
N13-4446

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not Used

NA: Uygulanamaz/Not applicable 1 / 2 10.06.13 / 270118-F39-02

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

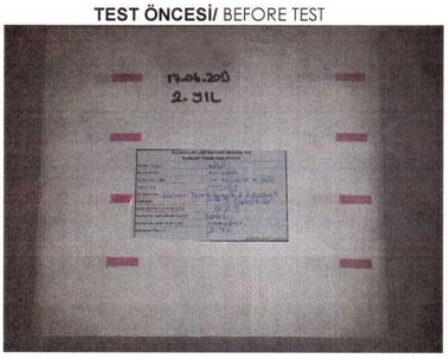
M13-1119
24.02.2014

❖ **ÖLÇÜM ANALİZ SONUÇLARI/** TEST RESULTS

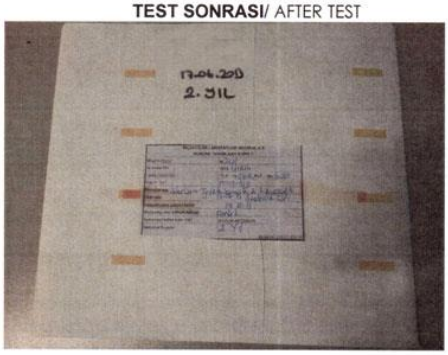
PARAMETRE	SONUÇ
Ambalaj Görünümü/ Packing View	UYGUN
Ürün Görünümü/ Product View	UYGUN

❖ **NUMUNE RESİMLERİ/** SAMPLE PHOTOS

TEST ÖNCESİ/ BEFORE TEST



TEST SONRASI/ AFTER TEST



❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Aysel YILDIRIM KİMYAGER		24.02.14
Laboratuar Onayı / Laboratory Approval:	Aysel YILDIRIM KİMYAGER		24.02.14
Kalite onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER		24.02.14
Mühür/Seal:			

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report
Bu rapor Bıçakcılar Laboratuarının yazılı onayı olmadan kısmen kopyalanamaz.
İmzasız ve mühürsüz raporlar geçersizdir.
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Testing reports without signature and seal are not valid

NA: Uygulanamaz/Not applicable 2 / 2 10.06.13 / 270118-F39–02

Annex 16 | H2O2 Indicator Accelerated Test Report (36 months)

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

İstiklal Mahallesi Atatürk Cad. No:21 Esenyurt İstanbul
Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep no:TLP-13-2600 Request no	**STABİLİTE İZLEME RAPORU** STABILITY MONITORING REPORT	M13-1120 28.03.2014
Teklif no:TLF-13-690 Tender no		
Kabul Tarihi:19.12.2013 Receiving Date		
Test başlangıç Tarihi:19.12.2013 Test Initiation Date:		
Test Bitiş Tarihi:26.03.2014 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

PMS MEDİKAL AMB.SAN.TİC.LTD.ŞTİ.
KARADUVAR MAH. SERBEST BÖLGE 11. CADDE NO: 46, AKDENIZ, 33020 MERSIN

❖ **TEST AMACI /** TEST TARGET

Testin hedefi, numunelerin yüksek sıcaklık ve nem etkisiyle hızlandırılmış olarak yaşlandırılmasını sağlamaktır
The target of this test is ensuring the samples accelerated aging by the effect of high temperature and humidity.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Cihaz No/Equipment No:LF020
Sıcaklık/Temperature: 58 ° C
Nem/Humidity:% 70
Müşteri tarafından beyan edilen depolama sıcaklığı:23 ° C
Warehousing temperature that is declared by customer:
Süre/Time:97 gün = 14 hafta=3 yıl

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Tyvek Sample2 -17.06.2013
N13-4447

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not Used

NA: Uygulanamaz/Not applicable 1 / 2 10.06.13 / 270118-F39-02

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

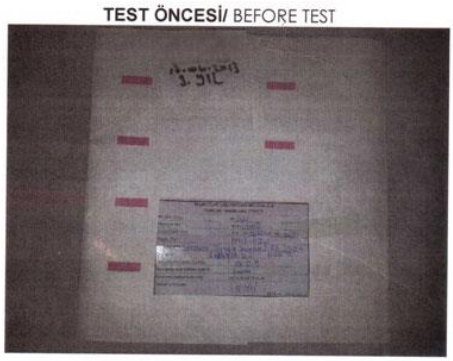
M13-1120
28.03.2014

❖ **ÖLÇÜM ANALİZ SONUÇLARI/** TEST RESULTS

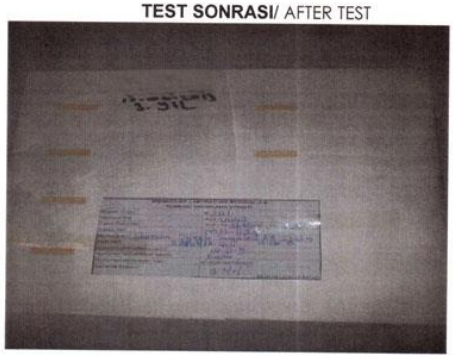
PARAMETRE	SONUÇ
Ambalaj Görünümü/ Packing View	NA
Ürün Görünümü/ Product View	UYGUN

❖ **NUMUNE RESİMLERİ/** SAMPLE PHOTOS

TEST ÖNCESİ/ BEFORE TEST



TEST SONRASI/ AFTER TEST



❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Aysel YILDIRIM KİMYAGER		28.03.14
Laboratuar Onayı / Laboratory Approval:	Aysel YILDIRIM KİMYAGER		28.03.14
Kalite onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER		28.03.14
Mühür/Seal:			

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report
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NA: Uygulanamaz/Not applicable

2 / 2

10.06.13 / 270118-F39–02

Annex 17 | Sterilization Efficacy Test Report

HIGHPOWER
Validation Testing & Lab Services

(585)-743-1930 • Fax (585)-697-1506
125 Highpower Road • Rochester NY, 14623 USA

FINAL REPORT

Confidential & Proprietary

Study No. 1410-584

STERILIZATION EFFICACY VALIDATION OF THE PMS TIP TYVEK® (TP) STERILIZATION POUCHES V-PRO® 1 PLUS LUMEN CYCLE (VHP)

Prepared for:

PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI
Mersin Tarsus Organize
Sanayi Bolgesi 12.Cad. No:2
Huzurkent/Mersin
TURKEY

Prepared by:

HIGHPOWER Validation Testing & Lab Services
125 Highpower Road
Rochester, NY 14623

Approved by:

Donald Tumminelli
Manager, Validation & Testing Services
HIGHPOWER Validation Testing & Lab Services

3/13/15
Date

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

Study No.:	1410-584
Sponsor:	PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI Mersin Tarsus Organize Sanayi Bolgesi 12.Cad. No:2 Huzurkent/Mersin, Turkey
Study Director:	Donald Tumminelli Manager, Validation & Testing Services
Report Prepared By:	Brian Smith – Microbiology Technician, Laboratory Services, B.S.
Study Personnel:	Brian Smith – Microbiology Technician, Laboratory Services, B.S.
Test Objective:	To verify the sterile efficacy of the PMS TIP Tyvek® (TP) Sterilization Pouches when processed in a V-PRO® 1 Plus Lumen sterilization cycle.
Test Samples:	PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1

References:

1. United States Pharmacopeia. Current Edition.
2. ANSI/AAMI ST24;1999(R)2009 Automatic General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended For Use in Health Care Facilities
3. ANSI/AAMI ST81:2004 (R2010) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
4. AAMI TIR12:2010; Designing, testing and labeling of reusable medical devices for reprocessing in healthcare facilities. A Guide for Device Manufacturers.
5. ANSI/AAMI/ISO 14937:2009/(R)2013; Sterilization of healthcare products – General requirements for characterization of a sterilizing agent and development, validation and routine control of a sterilization process.
6. Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA: released March 7, 2002.
7. HIGHPOWER Internal Standard Operating Procedures.

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

1.0 INTRODUCTION:

This report details the methods used in determining the sterilization efficacy of the PMS TIP Tyvek® (TP) Sterilization Pouches when processed in a Steris® V-PRO® 1 Plus Lumen sterilization cycle. A method of V-PRO® sterilization was validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. The SAL was achieved by inoculating with at least 1.0×10^6 spores of *Geobacillus stearothermophilus* in the most difficult to sterilize locations and sealing them within the Tyvek® (TP) Sterilization Pouches. The pouches were processed at one-half the expected full cycle exposure time. Following exposure, the BI's were aseptically transferred to culture media and incubated as required. This testing was repeated for a total of three (3) half cycles for each pouch size.

2.0 JUSTIFICATION:

The overkill method was selected to verify the sterilization efficacy of the PMS TIP Tyvek® (TP) Sterilization Pouches per AAMI and ISO guidelines. In this method, sterilization was accomplished by demonstrating that a minimum of 1.0×10^6 highly resistant *Geobacillus stearothermophilus* spores were killed in a half-cycle. A full cycle would therefore result in a 12-log reduction of spores and produce a 10^{-6} SAL, which reflects a one-in-a-million chance of a non-sterile item. This study provides the sponsor with sterilization data for the product. It is the responsibility of the sponsor to apply this data along with functionality and manufacturing data to the product label claims.

3.0 EQUIPMENT AND MATERIALS:

3.1 Test samples: PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1
3.2 Sterilizer: Steris® V-PRO® 1 Plus Sterilization System: Equipment # 508
3.3 Vaprox® HC 59% H_2O_2 Sterilant: Lot # HC3454R2
3.4 Medical Instruments and Simulated Instruments
3.5 SPSmedical Vaporized Hydrogen Peroxide chemical indicators, GPS-250R: Lot # 1406
3.6 Lumen devices
3.7 Pouch Divider
3.8 HEPA Laminar Flow Hood: Equipment # 209
3.9 Test Organism: *Geobacillus stearothermophilus* ATCC® 7953 biological indicator (BI)
  3.9.1 Micro paper strip: Batch # 140815M (from E14017)
  3.9.2 Wires: Batch # 141117W (from E14017)
3.10 Microbiological Culture Media
  3.10.1 Soybean Casein Digest Broth (SCDB): Lot # 14169
3.11 Incubator monitored and logged daily
  3.11.1 Calibrated at 55-60°C: Equipment # 254
3.12 Traceable Scale: Equipment # 025
3.13 Sterile Lab Transfer Equipment
3.14 Sterile Lab Transfer Attire

4.0 Steris® V-PRO® 1 PLUS LUMEN HALF CYCLE DESCRIPTION:

Each LUMEN CYCLE sterilization pulse was determined following condition phase ("C"). During Sterilization Phase ("S") found on printout and display screen, pressure rose in chamber to approximately 500 Torr followed by a vacuum which brought pressure to 0.4 Torr. This was one (1) sterilization pulse. After 2nd pulse to ~ 500 Torr and pump down to 0.4 Torr, cycle was immediately aborted.

5.0 VALIDATION OF CULTURE MEDIA:

All media was validated as required by the USP for sterility and growth promotion.

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

6.0 VALIDATION OF SPORES:

The biological indicators selected for testing were chosen for use based on their listed population, D-value, and actual test data from a compliant AAMI/ISO steam resistometer.

7.0 PROCEDURE:

7.1 Three (3) lumens each of the following sizes were inoculated: 1.5mm x 50.8mm, 3mm x 200mm and 3mm x 400mm, See Figure 1.

7.2 Two (2) 50 x 200mm sterilization pouches, two (2) 150 x 300mm and two (2) 350 x 600mm sterilization pouches from AGED samples and (1) 50 x 200mm, one (1) 150 x 300mm and one (1) 350 x 600mm sterilization pouch from UNAGED samples were obtained: See Bill of Materials, Table 1.

7.2.1 Each pouch was loaded with an inoculated lumen of the corresponding size along with one (1) BI and one (1) chemical indicator. The BI within the 350 x 600mm Pouch was ensured it was secured to the middle of the pouch. Additional instruments or dunnage were loaded into the pouch until full and then sealed. Each pouch was weighed and recorded (See Table 2).

7.3 All nine (9) pouches were placed into an otherwise empty sterilizer chamber, within a pouch divider and processed in the half cycle parameters in Section 4.0.

7.4 Following cycle completion, the pouches were removed to the Laminar Flow Hood.

7.5 As an environmental control, a vessel of culture media was uncapped within the Laminar Flow Hood during the transfer period.

7.6 The pouches were opened and all BI test samples were aseptically transferred to culture media.

7.7 Steps 7.2 through 7.6 were repeated two (2) additional times for a total of three (3) half cycles.

7.8 As positive controls, one (1) unprocessed BI from each lot used in testing was transferred to separate tubes of culture media and incubated with the test samples.

7.9 As a negative control, one (1) uninoculated tube of each type of culture media used in testing was utilized and incubated with the test samples.

7.10 All test samples and controls at 55-60°C were incubated for a minimum of fourteen (14) days.

7.11 Chemical indicators were observed for appropriate color change.

7.12 All results were recorded. See Table 3.

8.0 NEGATIVE VERIFICATION:

Following the full incubation period, media containing negative test samples was inoculated with ≤100 spores of *Geobacillus stearothermophilus* (low colony spore strips) and incubated for up to forty eight (48) hours for growth promotion. The presence of growth verified that the media could still support growth of a low number of the challenge organism and that bacteriostatic substances did not inhibit growth.

9.0 RESULTS:

9.1 All biological indicator test samples were negative for growth following the incubation period.

9.2 The positive controls were positive for growth.

9.3 The negative and environmental control demonstrated no growth.

9.4 The chemical indicators demonstrated a color change from red to yellow/orange.

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

10.0 DISCUSSION:

The Verify® V24 Self-Contained Biological Indicators (SCBI) were not utilized for testing as the SCBI does not allow for incubation periods of fourteen (14) days. Micro paper strip BI's were used in place of the SCBI's. This had no impact on results from testing as all BI's were assured at 1.0×10^6 *Geobacillus stearothermophilus* CFU's per BI prior to testing.

One deviation from the protocol was requested by the sponsor. This request was for all references to the company name as PMS Medikal to be changed to PMS TIP, and to also update the company address. These updates have been made and are reflected in this Final Report.

11.0 CONCLUSION:

Results from testing conclude that the PMS TIP Tyvek® (TP) Sterilization Pouches could achieve an SAL of 10^{-6} following processing in the V-PRO® 1 Plus lumen sterilization cycle.

BILL OF MATERIALS
PMS TIP TYVEK® (TP) STERILIZATION POUCHES

Pouch Size	Product Code	Lot #	Quantity*	Status
50 x 200 mm	TP 0520	3611	2	Aged
150 x 300 mm	TP 1530	3711	2	Aged
350 x 600 mm	TP 3560	3811	2	Aged
50 x 200 mm	TP 0520	4214	1	Unaged
150 x 300 mm	TP 1530	3214	1	Unaged
350 x 600 mm	TP 3560	4514	1	Unaged

TABLE I

*Quantities are per half cycle

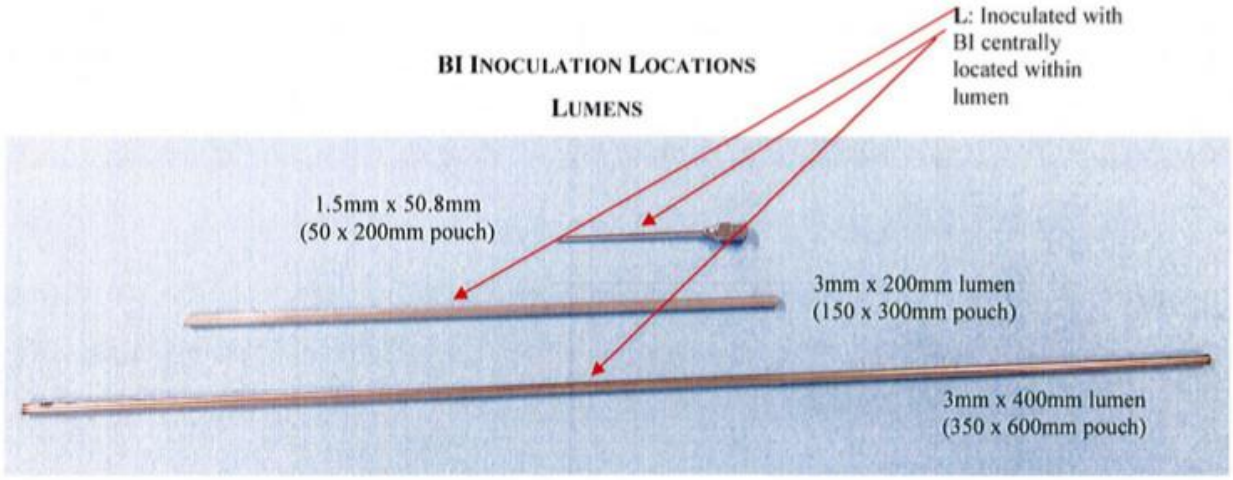

FIGURE I

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

Tyvek® (TP) Pouch Weights:

Pouch Size	Cycle # 1 (lbs.)	Cycle #2 (lbs.)	Cycle # 3 (lbs.)
50 x 200mm (Aged # 1)	0.054	0.048	0.056
50 x 200mm (Aged # 2)	0.056	0.052	0.052
50 x 200mm (Unaged)	0.052	0.058	0.054
150 x 300mm (Aged # 1)	0.622	0.618	0.614
150 x 300mm (Aged # 2)	0.618	0.618	0.626
150 x 300mm (Unaged)	0.630	0.626	0.630
350 x 600mm (Aged # 1)	3.042	3.032	3.042
350 x 600mm (Aged # 2)	3.036	3.018	3.036
350 x 600mm (Unaged)	3.018	3.054	3.020

TABLE 2

FINAL REPORT
HIGHPOWER Study No. 1410-584
PMS TIP
Tyvek® Pouches (TP) V-PRO® 1 Plus Lumen Cycle Efficacy Validation

BIOLOGICAL INDICATOR TEST RESULTS

SAMPLE ID		CYCLE #1	CYCLE #2	CYCLE #3
50 x 200mm (Aged # 1)	L	N	N	N
	BI	N	N	N
50 x 200mm (Aged # 2)	L	N	N	N
	BI	N	N	N
50 x 200mm (Unaged)	L	N	N	N
	BI	N	N	N
150 x 300mm (Aged # 1)	L	N	N	N
	BI	N	N	N
150 x 300mm (Aged # 2)	L	N	N	N
	BI	N	N	N
150 x 300mm (Unaged)	L	N	N	N
	BI	N	N	N
350 x 600mm (Aged # 1)	L	N	N	N
	BI	N	N	N
350 x 600mm (Aged # 2)	L	N	N	N
	BI	N	N	N
350 x 600mm (Unaged)	L	N	N	N
	BI	N	N	N
Environmental Control – SCDB 14169		N	N	N
Negative Control – SCDB 14169		N	N	N
Negative Verification – LG09		P	P	P
Positive Control – 141117W (from E14017)		P	P	P
Positive Control – 140815M (from E14017)		P	P	P

TABLE 3

N = Negative for Growth
P = Positive for Growth

Annex 18 | Bioburden Test Report

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.
Osmangazi Mah.Gazi Cad. No:21 Esenyurt İstanbul
Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep No: Request No	TLP-17-1288
Teklif No: Tender No	TLF-17-1288
Kabul Tarihi: Receiving Date	25.09.2017
Test Başlangıç Tarihi: Test Initiation Date	29.09.2017
Test Bitiş Tarihi: Test Final Date	07.10.2017

BİYOLOJİK YÜK
(Aerobik, Küf ve Maya)
DENEY RAPORU
BIOBURDEN
(Aerobic, Yeast and Mold)
TEST REPORT

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0052-T

AB-0052-T
M17-2360
12.10.2017

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SANAYİ VE TİCARET A.Ş.
KARADUVAR MAH.SERBEST BÖL. 11.CADDE NO:46 33020 MERSİN SERBEST BÖL.AKDENİZ/MERSİN

❖ **NUMUNEALMA METODU / SAMPLING METHOD**

Müşteri tarafından gönderilmiştir.

It was sent by the customer.

❖ **METOD TANIMI / METHOD DESCRIPTION**

İlk kez test edilen numune için ISO11737-1 standardında tanımlı olan geri kazanım metodları uygulandı ve geri kazanım faktörü belirlendi.
Microorganism recovery methods described in the ISO11737-1 standard have been applied for sample has been performed at first time and recovery factor has been determined.

Kullanılan TSA besiyeri aerobik bakteri üremesi için 30-35 C°'de 3-5 gün, mantar üremesi için 20-25°C'de 5-7 gün inkübe edilir. İnkübasyon sonrası koloni sayımı gerçekleştirilir. Geri kazanım faktörü ortalama mikroorganizma sayısı ile çarpılarak toplam mikroorganizma sayısı belirlenir.

TSA media used has been incubated in (to promote aerobically bacteria growth) at 30-35°C for 3-5 days and at 20-25°C(to promote yeast/molds) for 5-7 days . The growth microorganism has been counted after incubation. Number of total microorganism has been calculated by multiplying recovery factor and average microorganism number.

❖ **REFERANS STANDART/ REFERENCE STANDARD**

ISO 11737-1 Medikal cihazların sterilizasyonu- Mikrobiyolojik Methodlar-Ürün üzerindeki mikroorganizma popülasyonunun tanımlanması
Sterilization of medical devices-Microbiological methods-Part1: Determination of a population microorganisms on products

❖ **NUMUNE TANIMI - NUMUNE NO/** SAMPLE IDENTIFICATION - SAMPLE NO

TY2570 25cmx1mt- Lot:2617 - M17-2360-1

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

NA: Uygulanamaz/Not applicable 1/2 06.02.2017 / 270118-F06-07

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M17-2360
12.10.2017

❖ **NUMUNE ORANSAL PARÇASI/** S/P

%10

❖ **TEST SONUÇLARI /** TEST RESULTS

Numune Sample	Bakteri Sayısı Cfu/test edilen ürün sayısı Bacteria Number Cfu/ test item	Mantar/Küfler Cfu/test edilen ürün sayısı Yeast molds Cfu/ test item	Toplam mikroorganizma Sayısı Cfu/test edilen ürün sayısı Total microbial count Cfu/test item
1	5	0	5
Ortalama cfu/ Petri *Average cfu/ Plate*	5	0	5
*Ortalama cfu/ Ürün *Average cfu/ Device*	5	0	5

***Ortalama cfu/ Ürün = cfu/ Petri x Numune Oransal Parçası /**
Average cfu/ Device= cfu/ Plate X Sample Item Portion

Ortalama mikroorganizma sayısı x düzeltme faktörü=5*1,12= 5,6 kob/Ürün
Mean microbial count x correction factor=5*1,12= 5,6 cfu/Device

Bakteri Koloni Morfolojisi **Colony Morphology of Bacteria**	Bakteri Gram Boyama Sonuçları **Result of Bacteria Gram Stain**
Aerobik Bakteri / **Aerobic Bacteria**	
Krem Yuvarlak Koloni	Gram (+) Kok

❖ **LİMİTLER/** LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim-Ünvan	İmza	Tarih
Laboratuar Onay/ Laboratory Approval:	Aysel YILDIRIM KİMYAGER CHEMIST		12.10.17
Kalite Onay/ Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER CHEMIST		12.10.17
Mühür / Seal	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report

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Testing reports without signature and seal are not valid

NA: Uygulanamaz/ Not applicable 2/2 06.02.2017 / 270118-F06-07

Annex 19 | Microbial Aerosol Challenge Test Report

HIGHPOWER
Validation Testing & Lab Services

(585)-743-1930 • Fax (585)-697-1506
125 Highpower Road • Rochester NY, 14623 USA

FINAL REPORT

Confidential & Proprietary

Study No. 1311-569 Revision A

MICROBIAL AEROSOL CHALLENGE OF THE PMS MEDIKAL STERILIZATION POUCHES IN STERRAD 100NX

Prepared for:

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6/5/14
Date

FINAL REPORT
HIGHPOWER Study No. 1311-569 Revision A
PMS Medikal
Microbial Aerosol Challenge

Study No.:	1311-569 Revision A
Sponsor:	PMS Medikal Ambalaj San. ve Tic. Ltd. Şti. Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz, 33020 Mersin Turkey
Study Director:	Donald Tumminelli Manager, Validation & Testing Services
Study Personnel:	Joe Steinert – Validation Technician, Laboratory Services.
Report prepared By	Joe Steinert – Validation Technician
Test Objective:	To demonstrate that the microbial barrier property of PMS Medikal sterilization pouches can maintain sterility of contents following an aerosol challenge test.
Test Samples:	PMS Medikal sterilization pouches: See Bill of Materials, Table 1

References:

1. Pflug, IJ, and Holcomb, RG, "Principles of the Thermal Destruction of Microorganisms" in Disinfection, Sterilization and Preservation, (SS Block, ed). Lea & Febiger, Philadelphia, 4th edition, 1991.
2. United States Pharmacopeia. Current Edition.
3. Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA: released March 7, 2002
4. AAMI TIR12:2010 Designing testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
5. HIGHPOWER Internal SOP's
6. LSOP 072 Aerosol Challenge Procedure

FINAL REPORT
HIGHPOWER Study No. 1311-569 Revision A
PMS Medikal
Microbial Aerosol Challenge

1.0 INTRODUCTION:

This report details the methods used in determining the microbial barrier properties of the PMS Medikal International sterilization pouches following exposure to Sterrad 100NX Standard Cycle and then subjected to an aerosol of spores which challenged the packaging system. Each pouch was loaded with stainless steel coupons, a Biological Indicator (BI) and a chemical integrator (CI). Following exposure to a microbial aerosol challenge the BIs and stainless steel coupons were aseptically transferred to culture media and incubated as required. A total of three (3) pouches were tested.

2.0 JUSTIFICATION:

The use of the aerosol challenge test to analyze the microbial barrier properties of the PMS Medikal sterilization pouches is considered to be rigorous. By showering the pouches with an aerosol of spores, the permeability of the pouches to microorganisms is challenged. A sample which demonstrates that all items remain sterile following this test can be said to be safe and effective at maintaining sterility of its contents following sterile processing.

The use of the coupons is based on several considerations. First, they offer a convenient way to identify the specific pieces to be sterility tested and to confirm that test samples were placed in the specified locations. Second, coupons are relatively easy to manipulate and reduce the likelihood of the introduction of adventitious growth into the sterility test results. Third, the coupons are made of an identical metal as that used to manufacture medical instruments. This study provides the sponsor with sterilization data for the product. It is the responsibility of the sponsor to apply this data along with functionality and manufacturing data to the product label claims.

3.0 EQUIPMENT AND MATERIALS:

- 3.1 Test samples: PMS Medikal Sterilization Pouches: See Bill of Materials, Table 1
- 3.2 Sterrad 100NX HIGHPOWER I Equipment # 243
- 3.3 Stainless Steel Coupons
- 3.4 Pouch Divider
- 3.5 ASP Sterrad Chemical indicator strip: Lot # 171311-01
- 3.6 HEPA Laminar Flow Hood: HIGHPOWER Equipment # 045
- 3.7 Test Organism: *Bacillus atrophaeus* 9372
  - 3.7.1 Aerosol Suspension: Batch # 131125 from BT207
  - 3.7.2 Low Colony Spore Strips: Lot # LA12
- 3.8 STERRAD CycleSure BI Lot # 29513706
- 3.9 Microbiological Culture Media
  - 3.9.1 Tryptic Soy Broth (TSB): Batch # 131209-1
  - 3.9.2 Tryptic Soy Agar (TSA): Batch # 131210-1
- 3.10 USP Extraction Fluid: Batch # 131203-1
- 3.11 Incubator monitored and logged daily
  - 3.11.1 Calibrated at 30 - 37°C: HIGHPOWER Equipment # 253
  - 3.11.2 Calibrated at 55 - 60°C: HIGHPOWER Equipment # 254
- 3.12 Sterile Lab Transfer Equipment
- 3.13 Sterile Lab Transfer Attire
- 3.14 N.I.S.T. Traceable Timer: HIGHPOWER Equipment # 532

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4.0 STERRAD 100NX STANDARD CYCLE DESCRIPTION:

STERRAD® 100NX Sterilization System	
Standard Cycle Parameter Description	Transfer 1 = 8 minutes Diffusion 1 = 0.5 min Plasma 1 = 7.5 min Transfer 2 = 8 minutes Diffusion 2 = 0.5 min Plasma 2 = 7.5 min.
Injected hydrogen Peroxide	5400 µL of 59% H_2O_2

5.0 VALIDATION OF CULTURE MEDIA:

All media was validated as required by the USP for sterility and growth promotion.

6.0 PROCEDURE:

6.1 The PMS Medikal sterilization pouches were obtained: See Bill of Materials, Table 1.

6.2 Each pouch was seeded with five (5) stainless steel coupons, one (1) chemical indicator and one (1) biological indicator: See Figure 1.

6.3 The pouches were heat sealed and labeled.

6.4 The pouches were placed in the sterilizer chamber, the door was closed and the pouches were processed in the100NX Standard cycle stated in Section 4.0 of this report.

6.5 Following cycle completion, the pouches were removed from the sterilizer, placed on wire racks and allowed to cool.

6.6 The pouches were placed in the aerosol chamber.

6.7 Five (5) samples of 5 cm x 5 cm gauze were placed in the aerosol chamber on petri plates. One (1) sample was placed in each corner and one (1) in the center per Figure 2.

6.8 The pouches and gauze were subjected to a measured amount of aerosol containing approximately 1.0 x 10^7 *Bacillus atrophaeus* CFUs/mL in order to achieve an exposure of at least 800 CFUs per cm^2.

6.9 The gauze samples were assayed to determine the fallout.

6.10 Following aerosol challenge, the outside of each pouch was disinfected and removed to the laminar flow hood.

6.11 A tube of media was exposed within the laminar flow hood during the transfer process as an environmental control.

6.12 The coupons and BIs were aseptically transferred to microbiological culture media.

6.13 As positive controls, one (1) unprocessed BI from each lot used in testing was transferred to separate tubes of culture media and incubated with the test samples.

6.14 As a negative control, one uninoculated tube of each type of culture media used in testing was incubated with the test samples.

6.15 All BI test samples and controls were incubated at 55 - 60°C for seven (7) days. All coupon test samples were incubated at 30-37°C for seven (7) days.

6.16 Chemical indicators were observed for adequate H_2O_2 penetration.

6.17 The cycle printout tapes were verified.

6.18 All results were recorded: See Table 2.

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Microbial Aerosol Challenge

7.0 NEGATIVE VERIFICATION:

Following the full incubation period, negative test samples were inoculated with ≤100 spores of *Bacillus atrophaeus* and incubated for forty eight (48) hours per USP for growth promotion. The presence of growth verified the media could still support growth of a low number of the challenge organism and that bacteriostatic substances did not inhibit growth.

8.0 RESULTS:

8.1 The test sample coupons demonstrated no growth following incubation of test samples (Table 2).
8.2 All positive controls were positive for growth.
8.3 All negative and environmental controls were negative for growth (Table 2).
8.4 Fallout plates demonstrated the average fallout rate to be 752

9.0 CONCLUSION:

Based on the results of testing the PMS Medikal 200 X 400 sterilization pouches are an effective microbial barrier following a STERRAD 100NX, Standard Cycle and when subjected to an aerosol challenge.

BILL OF MATERIALS

Quantity	DESCRIPTION	Lot #
3	PMS Medikal Sterilization Pouches 200X 400 mm	2213

TABLE 1

SAMPLE LOAD CONFIGURATION
TOP VIEW OF POUCH

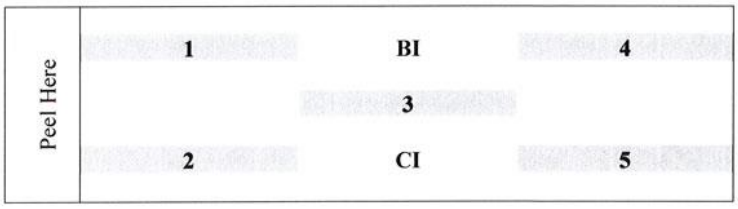

FIGURE 1

1-5 = Stainless Steel Coupons
BI = Biological Indicator
CI = Chemical Indicator

FINAL REPORT
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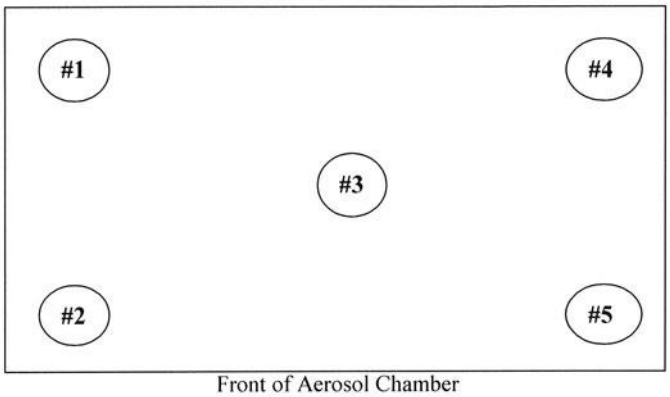
PMS Medikal
Microbial Aerosol Challenge

GAUZE PLACEMENT IN AEROSOL CHAMBER



Front of Aerosol Chamber

FIGURE 2

TEST RESULTS

Sample ID		Pouch # 1	Pouch # 2	Pouch # 3
LOT: 2213	1	N	N	N
	2	N	N	N
	3	N	N	N
	4	N	N	N
	5	N	N	N
	BI	N	N	N
Environmental Control – TSB 131209-1		N	N	N
Negative Control – TSB 131209-1		N	N	N
Positive Control –CycleSure BI		P	P	P
Negative Verification – LA12		P	P	P

TABLE 2

1 - 5 = Stainless Steel Coupons
BI = Biological Indicator
N = Negative for Growth
P = Positive for Growth

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Annex 20 | Cytotoxicity Test Report

HIGHPOWER
Validation Testing & Lab Services

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FINAL REPORT

Confidential & Proprietary

Study No. 1410-603-5

MEM ELUTION CYTOTOXICITY TESTING OF THE PMS TIP TYVEK® (TP) STERILIZATION POUCHES STERIS® V-PRO® 1 PLUS LUMEN CYCLE

Prepared for:

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3/5/15
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FINAL REPORT
HIGHPOWER Study No. 1410-603-5
PMS TIP Tyvek® (TP) Sterilization Pouches
MEM Elution Cytotoxicity Testing

Study No.:	1410-603-5
Sponsor:	PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI Mersin Tarsus Organize Sanayi Bolgesi 12.Cad. No:2 Huzurkent/Mersin TURKEY
Study Director:	Donald Tumminelli Manager, Validation & Testing Services
Study Personnel:	Kristen Van Buren – Validation Technician B.S.
Report Prepared By:	Kristen Van Buren – Validation Technician B.S.
Test Objective:	To test the cytotoxicity of the PMS TIP Tyvek® (TP) Sterilization Pouches following a V-PRO® 1 Plus lumen sterilization cycle.
Test Sample:	PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1

References:

1. United States Pharmacopeia/National Formulary, <87> Biological Reactivity Test, In Vitro; Elution Test.
2. ANSI/AAMI/ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity.
3. HIGHPOWER Internal Standard Operating Procedures
4. ANSI/AAMI/ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

FINAL REPORT
HIGHPOWER Study No. 1410-603-5
PMS TIP Tyvek® (TP) Sterilization Pouches
MEM Elution Cytotoxicity Testing

1.0 INTRODUCTION:

This report details the methods used in determining the cytotoxicity the PMS TIP Tyvek® (TP) Sterilization Pouches after being processed in a V-PRO® 1 Plus lumen sterilization cycle. Following cycle completion, the pouches were tested using an MEM Elution Cytotoxicity Assay per USP and ISO methods. All samples were pooled in one analysis.

2.0 JUSTIFICATION:

Cytotoxicity testing is a type of biocompatibility used to determine whether use of a medical device can have any potentially harmful physiological effects. This involves extracting leachable materials from the device or components and analyzing the leachable extracts for potentially harmful chemicals or cytotoxicity. Current regulations require that manufacturers conduct adequate safety testing of their finished devices as part of the regulatory process. It is the responsibility of the sponsor to apply this data along with functionality and manufacturing data to the product label claims.

3.0 EQUIPMENT & MATERIALS:

3.1 PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1
3.2 Sterilizer: Steris® V-PRO® 1 Plus Sterilization System: Equipment # 507
3.3 Vaprox® HC 59% H_2O_2 Sterilant: lot # HC3454R2
3.4 Chemical Indicators: Lot # 1412

4.0 STERIS® V-PRO® 1 PLUS LUMEN CYCLE DESCRIPTION:

Each LUMEN CYCLE sterilization pulse was determined following condition phase ("C"). During Sterilization Phase ("S") found on printout and display screen, pressure rose in chamber to approximately 500 Torr followed by a vacuum which brought pressure to 0.4 Torr. This was one (1) LUMEN CYCLE sterilization pulse. A full cycle consisted of four (4) pulses followed by a short aeration phase to complete the cycle.

5.0 PROCEDURE:

5.1 The PMS TIP Tyvek® (TP) Sterilization Pouches were obtained: See Bill of Materials, Table 1.
5.2 Each pouch was seeded with a chemical indicator.
5.3 The pouches were placed in sterilizer chamber, the sterilizer door was closed and the cycle stated in Section 4.0 was processed.
5.4 Chemical indicators were observed for a marked color change.
5.5 The cycle printout tapes were verified.
5.6 The pouches were tested per ISO 10993-5 MEM Elution Cytotoxicity Analysis at MOOG MDG, Rush NY:
  5.6.1 L929 mammalian fibroblast cells, acquired from a recognized repository (American Tissue Culture Collection; ATCC CCL 1, NCTC clone 929) were obtained.
  5.6.2 Standard positive controls (validated latex rubber) and standard negative controls (validated USP HDPE Reference Standard) were set up.
  5.6.3 The L929 cells were plated and incubated for a minimum of 24 hours in 37°C, 5% CO_2 humidified incubator to achieve a ~80% confluent monolayer.
  5.6.4 MEM Elution fluid, supplemented to contain 10% fetal bovine serum and an antibiotic/antimycotic were obtained.
  5.6.5 Samples were extracted within the MEM Elution fluid for 24 +/- 2 hours in accordance with ISO 10993-12:2012 at 37°C +/- 1°C.
  5.6.6 Following incubation, the L929 cell cultures were examined to ensure healthy subconfluent monolayers are present.

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PMS TIP Tyvek® (TP) Sterilization Pouches
MEM Elution Cytotoxicity Testing

5.6.7 The cell culture medium was aspirated from the plates.

5.6.8 Two (2.0) mL of MEM Elution extract from the test sample, was plated in triplicate with the L929 cells and incubated at 37°C +/- 1°C, 5% CO_2 incubator for 48 +/- 2 hours.

5.6.9 The test samples were graded following the reactivity grading system in ISO 10993-5 for qualitative morphological reactivity: See Table 2.

5.7 All results were recorded.

6.0 RESULTS:

6.1 The PMS TIP Tyvek® (TP) Sterilization Pouches scored a grade of zero (0).

6.2 All positive controls scored a grade of three (3).

6.3 All negative controls scored a grade of zero (0).

6.4 The chemical indicators demonstrated a color change from red to blue.

7.0 DISCUSSION:

A deviation from the protocol was requested by the sponsor. All references to the company name as PMS Medikal were changed to PMS TIP as well as an update to the company address. These updates have been made and are reflected in this Final Report.

8.0 CONCLUSION:

The test samples meet the USP and ISO 10993-5 requirements for this test. All controls were acceptable and the test considered valid. The test samples PASSED and are considered NON-TOXIC under the test conditions employed.

PMS TIP TYVEK® (TP) STERILIZATION POUCHES

Pouch Size	Product Code	Lot #	Quantity*	Status
50 x 200 mm	TP 0520	3611	1	Aged
150 x 300 mm	TP 1530	3711	1	Aged
350 x 600 mm	TP 3560	3811	1	Aged
50 x 200 mm	TP 0520	4214	1	Unaged
150 x 300 mm	TP 1530	3214	1	Unaged
350 x 600 mm	TP 3560	4514	1	Unaged

TABLE 1

FINAL REPORT
HIGHPOWER Study No. 1410-603-5
PMS TIP Tyvek® (TP) Sterilization Pouches
MEM Elution Cytotoxicity Testing

CYTOTOXICITY REACTIVITY GRADING SYSTEM

Grade	Reactivity	Conditions of all Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology, occasional lysed cells are present, only slight growth inhibition observable
2	Mild	No more than 50% of the cells are round, devoid of intracytoplasmic granules, no extensive cell lysis, not more than 50% growth inhibition observable
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable
4	Severe	Nearly complete or complete destruction of the cell layers

TABLE 2

Annex 20 | Burst Test Report

HIGHPOWER
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FINAL REPORT

Confidential & Proprietary

Study No. 1410-600

BURST TESTING OF THE PMS TIP TYVEK® (TP) STERILIZATION POUCHES STERIS® V-PRO® 1 PLUS LUMEN CYCLE

Prepared for:

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3/23/15
Date

FINAL REPORT
HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

Study No.:	1410-600
Sponsor:	PMS TIP TEKNOLOJILERI SAN VE TIC LTD STI Mersin Tarsus Organize Sanayi Bolgesi 12.Cad. No:2 Huzurkent/Mersin TURKEY
Study Director:	Don Tumminelli Manager, Validation & Lab Services
Study Personnel:	Kristen Van Buren – Validation Technician B.S.
Report Prepared By:	Kristen Van Buren – Validation Technician B.S.
Test Objective:	To test the burst value of the PMS TIP Tyvek® (TP) Sterilization Pouches following processing in a V-PRO® 1 Plus lumen sterilization cycle per ASTM F1140.
Test Sample:	PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1

References:

1. United States Pharmacopeia. Current Edition.
2. ANSI/AAMI ST8:2013; Hospital Steam Sterilizers.
3. ANSI/AAMI ST79:2010/A4:2013; Comprehensive guide to steam sterilization and sterility assurance in health care facilities
4. ASTM F1140/F1140M-13; Internal Pressurization Failure Resistance of Unrestrained Packages
5. HIGHPOWER Internal Standard Operating Procedures

FINAL REPORT
HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

1.0 INTRODUCTION:

This report details the methods used in determining the ability of the PMS TIP Tyvek® (TP) Sterilization Pouches to withstand internal pressurization after being processed in a V-PRO® 1 Plus lumen sterilization cycle. Following processing, the pouches were subjected to internal pressure, by introducing air into the sealed pouch until it failed, or burst. The measure of the test is the maximum pressure detected before the pouches burst. The analysis was performed following ASTM F1140: Internal Pressurization Failure Resistance of Unrestrained Packages.

2.0 JUSTIFICATION:

Burst testing provides a quick means of assessing tendencies for a pouch to fail when it is exposed to a pressure differential. Pressure differentials may occur within a package during different situations, such as sterilization and transportation. It is important to ensure that the package can maintain integrity and therefore sterility throughout all reasonable circumstances. It is the responsibility of the sponsor to apply this data along with functionality and manufacturing data to the product label claims.

3.0 EQUIPMENT & MATERIALS:

3.1 PMS TIP Tyvek® (TP) Sterilization Pouches: See Bill of Materials, Table 1
3.2 Sterilizer: Steris® V-PRO® 1 Plus Sterilization System: Equipment # 508
3.3 Vaprox® HC 59% H_2O_2 Sterilant: Lot # HC3224P4
3.4 Chemical Indicators: Lot # 1406
3.5 Burst Testing Apparatus

4.0 STERIS® V-PRO® 1 PLUS LUMEN CYCLE DESCRIPTION:

Each LUMEN CYCLE sterilization pulse was determined following condition phase ("C"). During Sterilization Phase ("S") found on printout and display screen, pressure rose in chamber to approximately 500 Torr followed by a vacuum which brought pressure to 0.4 Torr. This was one (1) LUMEN CYCLE sterilization pulse. A full cycle consisted of four (4) pulses followed by a short aeration phase to complete the cycle.

5.0 PROCEDURE:

5.1 The PMS TIP Tyvek® (TP) Sterilization Pouches were obtained: See Bill of Materials, Table 1.
5.2 Each pouch was seeded with one (1) chemical indicator.
5.3 The pouches were sealed and placed within the sterilizer chamber and processed for the cycle stated in Section 4.0.
5.4 All chemical indicators were assessed for a marked color change.
5.5 Following cycle completion the pouches were subjected to an increase in internal pressure by introducing air into the pouch until it bursts. At that point, the pressure reading was recorded.
5.6 The cycle printout tapes were verified.
5.7 All results were recorded: See Tables 2 thru 7 and Figure 1.

6.0 DISCUSSION:

6.1 A typographical error was noted in the Bill of Materials, Table 1, of the Protocol stating that one (1) of each pouch was to be tested. It has been updated in this Final Report to show that three (3) of each type of pouch were actually tested.
6.2 A deviation from the protocol was requested by the sponsor. All references to the company name as PMS Medikal were changed to PMS TIP as well as an update to the company address. These updates have been made and are reflected in this Final Report.

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PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

6.3 Three (3) of each lot of unprocessed pouch from Table 1 were also burst tested. Results are recorded in Tables 5 thru 7.

1.0 CONCLUSION:

Conclusions to be drawn by sponsor.

BILL OF MATERIALS
PMS TIP TYVEK® (TP) STERILIZATION POUCHES

Pouch Size	Product Code	Lot #	Quantity	Status
50 x 200 mm	TP 0520	3611	3	Aged
150 x 300 mm	TP 1530	3711	3	Aged
350 x 600 mm	TP 3560	3811	3	Aged
50 x 200 mm	TP 0520	4214	3	Unaged
150 x 300 mm	TP 1530	3214	3	Unaged
350 x 600 mm	TP 3560	4514	3	Unaged

TABLE 1

TEST RESULTS – PROCESSED POUCHES

TYVEK STERILIZATION POUCH TP 0520

Test Parameters:	Pressure: 14.0 psig	Timer: 2.0 seconds	Flow Rate: 7, Porous
Sample ID		Burst Pressure (psig)	Location (s)
Lot # 4214	1	5.40	A, J
	2	4.60	D
	3	5.52	I
Average:		5.17	N/A
Standard Deviation:		0.50	N/A
Lot # 3611	1	4.58	D, E
	2	2.52	I, H
	3	3.62	I, H
Average:		3.57	N/A
Standard Deviation:		1.03	N/A

TABLE 2

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HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

TYVEK STERILIZATION POUCH TP 1530

Test Parameters:	Pressure: 25.0 psig	Timer: 3.0 seconds	Flow Rate: 8, Porous
Sample ID		Burst Pressure (psig)	Location (s)
Lot # 3711	1	1.74	I
	2	1.92	D
	3	1.90	I, H
Average:		1.85	N/A
Standard Deviation:		0.10	N/A
Lot # 3214	1	1.58	D
	2	1.50	I
	3	1.64	D
Average:		1.57	N/A
Standard Deviation:		0.07	N/A

TABLE 3

TYVEK STERILIZATION POUCH TP 3560

Test Parameters:	Pressure: 50.0 psig	Timer: 4.0 seconds	Flow Rate: 16, Porous
Sample ID		Burst Pressure (psig)	Location (s)
Lot # 3811	1	4.86	A, B
	2	4.44	D, E
	3	4.69	C, D, E
Average:		4.66	N/A
Standard Deviation:		0.21	N/A
Lot # 4514	1	3.20	D, E
	2	5.80	D
	3	4.60	E
Average:		4.53	N/A
Standard Deviation:		1.30	N/A

TABLE 4

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HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

TEST RESULTS – UNPROCESSED POUCHES

TYVEK STERILIZATION POUCH TP 0520

Test Parameters:	**Pressure: 12.5 psig**	**Timer: 2.0 seconds**	**Flow Rate: 13, Porous**
Sample ID		**Burst Pressure (psig)**	**Location (s)**
Lot # 4214	1	2.28	C, D
	2	2.98	D
	3	3.22	I
Average:		2.83	N/A
Standard Deviation:		0.49	N/A
Lot # 3611	1	3.28	I, H
	2	2.78	D
	3	3.60	D
Average:		3.22	N/A
Standard Deviation:		0.41	N/A

TABLE 5

TYVEK STERILIZATION POUCH TP 1530

Test Parameters:	**Pressure: 25.0 psig**	**Timer: 3.0 seconds**	**Flow Rate: 8, Porous**
Sample ID		**Burst Pressure (psig)**	**Location (s)**
Lot # 3711	1	1.68	D
	2	1.94	I, H
	3	1.70	D, E
Average:		1.77	N/A
Standard Deviation:		0.14	N/A
Lot # 3214	1	1.94	C, D
	2	1.68	D
	3	1.96	D, E
Average:		1.86	N/A
Standard Deviation:		0.16	N/A

TABLE 6

FINAL REPORT
HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

TYVEK STERILIZATION POUCH TP 3560

Test Parameters:	Pressure: 50.0 psig	Timer: 4.0 seconds	Flow Rate: 16, Porous
Sample ID		Burst Pressure (psig)	Location (s)
Lot # 3811	1	5.78	D, E
	2	5.56	D, E
	3	5.80	A
Average:		5.71	N/A
Standard Deviation:		0.13	N/A
Lot # 4514	1	6.44	D
	2	6.22	D
	3	6.16	D
Average:		6.27	N/A
Standard Deviation:		0.15	N/A

TABLE 7

FINAL REPORT
HIGHPOWER Study No. 1410-600
PMS TIP Tyvek® (TP) Sterilization Pouches
Burst Testing

BURST TEST LOCATIONS

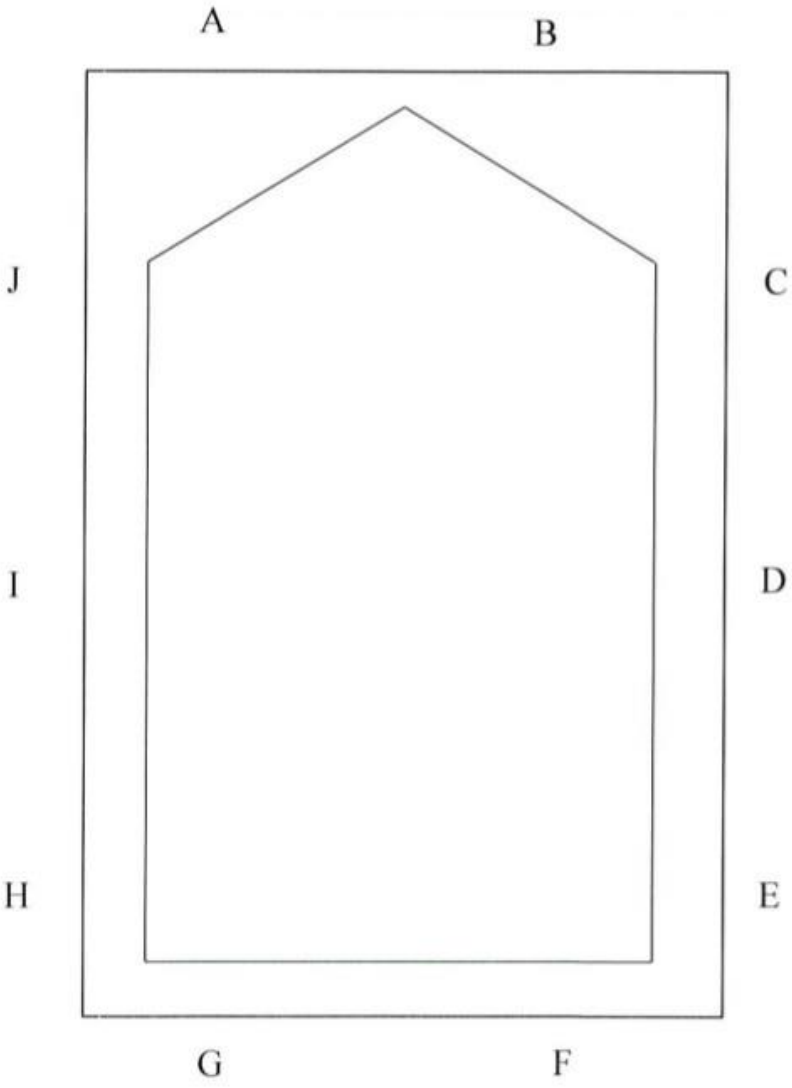

FIGURE 1

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