Product Handbook I

Sterilization Reels & Pouches

www.pmsmedikal.com

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 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 various certificates, test reports from independent laboratories and product related documentation.

About PMS

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

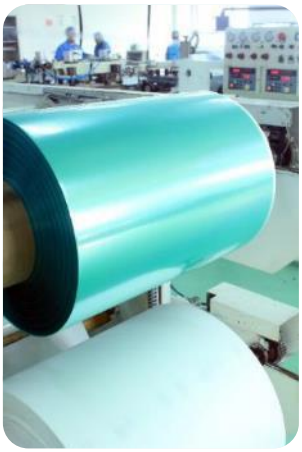
PMSSteripack®

PMSSteriSeal™

PMSSteriTest™

Operating in more than 70 countries in five continents and with production plants in international standards in Turkey, Germany and India, PMS is taking solid steps towards becoming a global player with its strategic and global collaborations and more competitive and innovative approach.

Manufacturing Process



PMSSteripack 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 applies the valid Environmental, Health and Safety regulations of Turkey. The regulations instructions are followed when processing material, operating machinery and other equipment which is used during the manufacturing of 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 conform steam resistometers.

Contents

1. Product Description

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

PMSSteripack Sterilization packaging is constructed of transparent multilayer PET/PP copolymer film web and medical grade paper in compliance with EN 868-3. Chemical process indicators are applied on the paper surface for intended sterilization methods.

Standard PMSSteripack sterilization packaging is constructed of 60gr medical grade paper with steam and ethylene oxide process indicators and PET/PP film web.

PMSSteripack sterilization packaging is available with 60gr and 70gr medical grade paper and with selectable imprinted chemical process indicator for steam, ethylene oxide and formaldehyde sterilization methods. For additional product design requests please contact us at pms@pmsmedikal.com or through your customer representative responsible for your area.

- Annex 3 | TSE EN 868-5 Certification
- Annex 4 | Technical Data Sheet Sterilization Reel
- Annex 5 | Technical Data Sheet Sterilization Pouch
- Annex 6 | CE Declaration of Conformity

1.1 Intended Use

PMSSteripack sterilization reels and pouches are intended for use at packaging of medical devices to be sterilized in steam, ethylene oxide or formaldehyde sterilizers. Sterilization packaging will maintain its sterility until point of use.

1.2 Sterilization Method

PMSSteripack sterilization reels and pouches are designed to be used at steam, ethylene oxide and formaldehyde 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.

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 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/PP film web
- Clean peel for aseptic presentation
- Proven microbial barrier properties
- Lead free water based chemical indicator
- Clear and accurate indicator color change
- Wide range of product sizes and types

1.4 Instructions for Use

PMSSteripack sterilization pouches are ready for use. 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 sterilization packaging is suitable for sealing between 180°C up to 190°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 sterilization reels and pouches are not designed to be used in dry heat, vaporized hydrogen peroxide gas plasma and gamma 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 sterilization reels and pouches are available in different types and dimensions to meet requirements of various medical devices to be packed and sterilized further.

Sterilization FLAT Reels (FL)		
Item Code	**Dimension**	**Units/Box**
FL05200	5cm x 200m	12
FL75200	7.5cm x 200m	8
FL10200	10cm x 200m	6
FL15200	15cm x 200m	4
FL20200	20cm x 200m	4
FL25200	25cm x 200m	2
FL30200	30cm x 200m	2
FL40200	40cm x 200m	2
FL50200	50cm x 200m	2

Sterilization GUSSETED Reels (GS)		
Item Code	**Dimension**	**Units/Box**
GS75100	7.5cm x 100m	8
GS10100	10cm x 100m	6
GS15100	15cm x 100m	4
GS20100	20cm x 100m	4
GS25100	25cm x 100m	2
GS30100	30cm x 100m	2
GS35100	35cm x 100m	2
GS40100	40cm x 100m	2

Sterilization GUSSETED Pouches (GP)		
Item Code	**Dimension**	**Units/Box**
GP7525	7.5cm x 25cm	1.000
GP1030	10cm x 30cm	1.000
GP1039	10cm x 39cm	1.000
GP1045	10cm x 45cm	1.000
GP1530	15cm x 30cm	1.000
GP1539	15cm x 39cm	1.000
GP2039	20cm x 39cm	500
GP2045	20cm x 45cm	500
GP2050	20cm x 50cm	500
GP2545	25cm x 45cm	500
GP2550	25cm x 50cm	500
GP3060	30cm x 60cm	500
GP4060	40cm x 60cm	500

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

Sterilization FLAT Pouches (FP)		
Item Code	**Dimension**	**Units/Box**
FP0525	5cm x 25cm	1.000
FP7520	7.5cm x 20cm	1.000
FP7525	7.5cm x 25cm	1.000
FP7530	7.5cm x 30cm	1.000
FP7535	7.5cm x 35cm	1.000
FP7540	7.5cm x 40cm	1.000
FP1020	10cm x 20cm	1.000
FP1025	10cm x 25cm	1.000
FP1030	10cm x 30cm	1.000
FP1035	10cm x 35cm	1.000
FP1040	10cm x 40cm	1.000
FP1050	10cm x 50cm	1.000
FP1060	10cm x 60cm	1.000
FP1230	12cm x 30cm	1.000
FP1520	15cm x 20cm	1.000
FP1525	15cm x 25cm	1.000
FP1530	15cm x 30cm	1.000
FP1535	15cm x 35cm	1.000
FP1540	15cm x 40cm	1.000
FP1550	15cm x 50cm	1.000
FP2040	20cm x 40cm	1.000
FP2060	20cm x 60cm	1.000
FP2128	21cm x 28cm	1.000
FP2135	21cm x 35cm	1.000
FP2142	21cm x 42cm	1.000
FP2535	25cm x 35cm	1.000
FP2540	25cm x 40cm	1.000
FP2545	25cm x 45cm	1.000
FP2550	25cm x 50cm	1.000
FP2835	28cm x 35cm	1.000
FP2840	28cm x 40cm	1.000
FP2850	28cm x 50cm	1.000
FP3040	30cm x 40cm	1.000
FP3045	30cm x 45cm	1.000
FP3050	30cm x 50cm	1.000
FP3060	30cm x 60cm	1.000
FP3250	32cm x 50cm	1.000
FP3550	35cm x 50cm	1.000
FP3660	36cm x 60cm	1.000
FP4060	40cm x 60cm	1.000
FP4250	42cm x 50cm	1.000
FP4255	42cm x 55cm	1.000
FP4260	42cm x 60cm	1.000

2. Medical Grade Paper

Medical grade paper with highest microbial barrier properties is used as bottom web for PMSSteripack sterilization packaging. The dense and matted layer structure of cellulosic fibers allows the sterilization agent to pass inside the package and creates at the same time a blocking path for microorganism after sterilization.

PMSSteripack medical grade paper are available in 60gr or 70gr and are suitable for steam, ethylene oxide and formaldehyde sterilization methods.

2.1 Properties Medical Grade Paper

PMS uses highest quality medical grade paper for PMSSteripack branded sterilization reels and pouches. Medical grade paper is in compliance to requirements defined by European Standard EN 868-3 and all requirements listed in below table are fulfilled at any time.

Properties	Unit	Related Standard	Value
Substance	g/m^2	ISO 536	60
Thickness	µm	ISO 534	83
Bendsten Porosity	ml/min	ISO 5636-3	1000
Air Permeance	µm/(Pa.s)	ISO 5636-3	11,4
Bendsten Roughness FS	ml/min	ISO 8791-2	375
Bendsten Roughness WS	ml/min	ISO 8791-2	375
Tensile Strength /MD	kN/m	EN ISO 1942-2	64
Tensile Strength /CD	kN/m	EN ISO 1942-2	3,4
Wet Tensile Strength /MD	kN/m	ISO 3781	2,1
Wet Tensile Strength /CD	kN/m	ISO 3781	1,1
Burst Strength	kPA	ISO 2758	350
Tearing Strength /MD	mN	ISO 1974	600
Tearing Strength /CD	mN	ISO 1974	650
Wet Burst	kPa	ISO 3689	150
Water Repellency	s	EN 868-2 (App. D)	35
Pore Size	µm	EN 868-2 (App. E)	21
COBB Test (60s)	g/m^2	ISO 535	15
Fluorescence	pts/dm^2	EN 868-2 (App. B)	0
pH: between 5.0 and 8.0 (ISO 6588-2)			
Chloride Content <0,05% (ISO 9197)			
Sulfate Content: <0,25% (ISO 9198)			
Free From Lead And Heavy Metals And Toxic Materials			

3. Chemical Indicator

PMSSteripack sterilization reels and pouches are imprinted with water based, non-toxic Class 1 chemical process indicators. The indicators are in compliance with ISO 11140-1 and fulfill the requirements of related standard.

PMSSteripack standard sterilization packaging is imprinted with steam and ethylene oxide chemical process indicators. Chemical indicator for formaldehyde sterilization method is available upon request.

3.1 Color Change of Chemical Indicators

PMSSteripack chemical process indicators provide a clear and accurate color change after successful sterilization.

Sterilization Method	PRE Sterilization	POST Sterilization
Steam		
Ethylene Oxide		
Formaldehyde		

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 chemical process indicators are tested by an independent laboratory for performance requirements according ISO 111401-1.

3.2.1 Steam Indicator Performance Testing

The test results obtained by an independent test laboratory verify that PMSSteripack steam chemical process indicators fulfill the performance requirements defined by ISO 11140-1.

- *Annex 7 | Steam Chemical Indicator Testing Report*

Testing Results Per ANSI/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	Test Result
Saturated Steam (Pass Cycle)	10.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	3.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Pass Cycle)	2.0 min ± 5 sec	134°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	0.5 min ± 5 sec	134°C (+3/0°C)	Acceptable
Dry Heat	30.0 min ± 1 min	140°C (+2/0°C)	Acceptable

3.2.2 Ethylene Oxide Indicator Performance Testing

The test results obtained by an independent test laboratory verify that PMSSteripack ethylene oxide chemical process indicators fulfill the performance requirements defined by ISO 11140-1.

- *Annex 8 | EO Chemical Indicator Testing Report*

Testing Results Per ANSI/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	RH%	Gas Concentration mg/L	Results
Absence of EO gas	90 min ± 1 min	60°C ± 2°C	≥ 85%	None	Acceptable Result
EO gas Test at:	5 min ± 15 sec	30°C ± 1°C	60 % ± 10% RH	600 mg/L ± 30 mg/L	Acceptable Result
	2 min ± 15 sec	54°C ± 1°C			
EO gas test at:	30 min ± 15 sec	30°C ± 1°C	60% ± 10 % RH	600 mg/L ± 30 mg/L	Acceptable Result
	20 min ± 15 sec	54°C ± 1°C			

3.2.3 Formaldehyde Indicator Performance Testing

The test results obtained by an independent test laboratory verify that PMSSteripack formaldehyde chemical process indicators fulfill the performance requirements defined by ISO 11140-1.

- *Annex 9 | FO Chemical Indicator Testing Report*

Testing Results Per Ansi/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	Gas Concentration mol/L	Results
Absence of formaldehyde	90 min ± 1 min	80°C ± 2°C	None	Acceptable Result
Formaldehyde:	20 s ± 5 s	60°C ± 0.5°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result
Formaldehyde	15 min ± 15 sec	70°C ± 2°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result

4. Laminated PET/PP Film Web

The film web used for PMSSteripack sterilization reels and pouches are constructed of transparent, reinforced multilayer (five) laminated PET/PP (Polyester/Polypropylene) film. PMS is one of three global manufacturers specialized for PP film extrusion for steam sterilization.

PMS developed a special PP film for steam sterilization with exceptionally sealing performance by increased bondability, tensile strength and melting point. PMSSteripack PET/PP films provide excellent mechanical strength, are easy sealable and peelable with uncoated medical grade paper.

The special film ensures high puncture, tear and break resistance pre and POST steam sterilization. PET/PP film web is suitable for steam, ethylene oxide and formaldehyde sterilization methods.

4.1 Properties of PET/PP Film Web

PMS uses highest quality PET/PP film webs for PMSSteripack branded sterilization reels and pouches. 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.

Properties	Unit		Method	Typical Value	
Thickness	µm		ISO 534	Lam. Film	53 ± 5
				PP	40 ± 5
				PET	12 ± 2
COF	F/M		ASTM F1894	0,30 – 0,35	
	M/M			0,35 – 0,40	
Thermal Seal	°C		ASTM F2029	150 ± 5	
Tear	G	MD	ASTM D1922	40 ± 5	
		TD		50 ± 5	
Gloss	%		ASTM D2457	150 ± 5	
Free From Lead And Heavy Metals And Toxic Materials					

5. Final Product Testing

PMS first priority is to meet customer expectations by highest quality and standard conform 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 sterilization packaging are tested for 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 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
Steam Indicator Control	pcs	Color change from pink to brown	Visual	Each printed roll
EO Indicator Control	pcs	Color change from green to yellow	Visual	Each incoming material lot
FO Indicator Control	pcs	Color change from pink to green	Visual	Each incoming material lot
PET/PP film Bond Strength	N/15mm	>2,7 n/15 mm	ASTM F88	Each film roll
PET/PP film Delaminating	pcs	None Allowed	Steam Ster. 134 °C/ 3,5min.	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 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 sterilization reels and pouches have been tested for bioburden after manufacturing process according ISO 11373-1 standard by an independent and accredited test laboratory. PMSSteripack sterilization packaging are produced in a controlled and clean environment and provide a safe and effective barrier against microorganism by no bacteria growth.

- Annex 10 | Bioburden Test Report FL10200
- Annex 11 | Bioburden Test Report GS15100
- Annex 12 | Bioburden Test Report FP15195
- Annex 13 | Bioburden Test Report GP1030

5.3 Microbial Barrier Properties

PMSSteripack sterilization reels and pouches are proven and effective microbial barriers. Microbial aerosol challenge test has been used for determining the microbial barrier properties of sterilization reels and pouches after steam sterilization. The test has been applied by an independent and accredited laboratory in USA.

- *Annex 14 | Microbial Aerosol Challenge Test Report*

TEST RESULTS

Sample ID		Pouch # 1	Pouch # 2	Pouch # 3
LOT: 1613	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 – RU39		P	P	P
Negative Verification – LA12		P	P	P

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

5.4 Product Ageing Studies

PMS has applied product ageing studies for establishing the product shelf life of PMSSteripack 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.

5.4.1 Accelerated Ageing

PMSSteripack sterilization reels and pouches have a product shelf life of 5 (five) years under recommended storage and handling conditions. Accelerated ageing study valid for 5 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 internal at PMS laboratory.

5.4.2 Natural Ageing

Natural ageing is essential for verification of test results obtained after accelerated ageing. PMSSteripack sterilization reels and pouches are stored under controlled and monitored environment and product physical property tests applied in a 6, 12, 18, 24, 36, 48, and 60 monthly period.

All data resulting from the testing have been evaluated and kept under record. The test results verify the shelf life of 5 (five) years for PMSSteripack sterilization reels and pouches under recommended storage conditions.

6. Product Packaging

The product packaging of PMSSteripack 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 sterilization pouches is done in bundles of 250/200 or 100 pieces depending on pouch dimension and wrapped with PP film. Sterilization reels of 100 or 200 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 sterilization reel and pouch is provided with a LOT number printed on the medical grade paper web. The LOT number allows the traceability of the product during the manufacturing process.

The LOT number is coded as following;

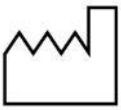
LOT WWYY

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

6.2 Expiry Date / Shelf Life

The shelf life of PMSSteripack sterilization reels and pouches are 5 (five) years after manufacture date under recommended storage and handling conditions.

The product must be used within 5 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.



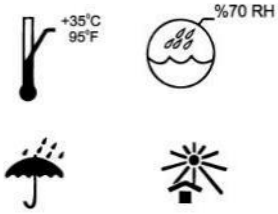
Manufacture Date Symbol
dd.MM.yy

Expiry Date Symbol
dd.MM.yy

6.3 Storage Conditions

PMSSteripack 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.

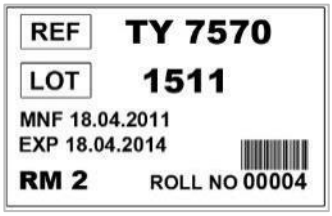


- Stored in original packaging
- Stored under controlled temperature (max. 35°C)
- Stored under controlled humidity (max. %70 Relative Humidity)
- Stored protected from direct sunlight, moisture and excessive airflow

6.4 Product Traceability Label

Each 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;

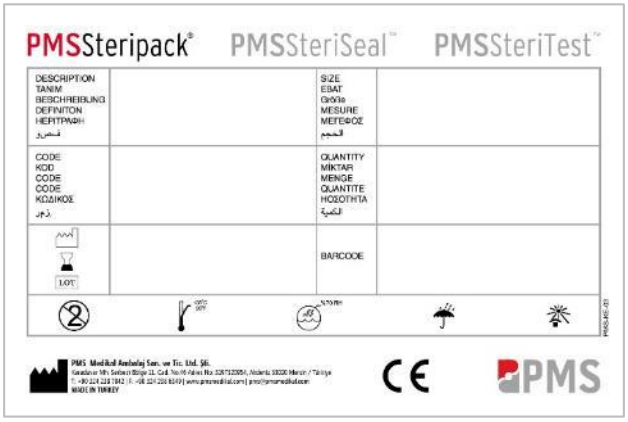
- Product Item Code (Ref.)
- Lot Number
- Manufacture Date
- Expiry Date
- Machine No
- Roll / Pouch Bundle No
- Product specific barcode



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 MEDİKAL AMB. SAN. TİC. LTD. ŞTİ.
Karaduvar Mah. Serbest Bölge 11. Cad. No: 46 33020 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 Sterilization Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes ,Bowie-Dick Test Packs ,Sealing Machines, Autoclavable Biohazard Bags

Approval
Certificate No: IST6008159/A

Original Approval: 22 November 2009
Current Certificate: 02 December 2013
Certificate Expiry: 01 December 2016

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

UKAS MANAGEMENT SYSTEMS
001

This document is subject to the provision on the reverse
71 Fenchurch Street, London EC3M 4BS United Kingdom. Registration number 1879370
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 13

Annex 2 | ISO 13485 Certification

Lloyd's Register LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

PMS MEDİKAL AMB. SAN. TİC. LTD. ŞTİ.
Karaduvar Mah. Serbest Bölge 11. Cad. No: 46 33020 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 Sterilization Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes, Bowie-Dick Test Packs Autoclavable Biohazard Bags (Class1)

Approval
Certificate No: IST6008159/B

Original Approval: 22 November 2009
Current Certificate: 02 December 2013
Certificate Expiry: 01 December 2016

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

UKAS MANAGEMENT SYSTEMS
001

This document is subject to the provision on the reverse
71 Fenchurch Street, London EC3M 4BS United Kingdom. Registration number 1879370
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

Annex 3 | 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 veya/or TSE

BELGE NUMARASI *REFERENCE NUMBER OF LICENCE*	14.0.30.4.01.00/TSE-15688
BELGENİN İLK VERİLİŞ TARİHİ *DATE OF FIRST ISSUE OF LICENCE*	27.10.2003
BELGENİN SON GEÇERLİLİK TARİHİ *LICENCE VALID UNTIL*	27.10.2014
BELGE SAHİBİ KURULUŞUN ADI *NAME OF THE LICENCE HOLDER*	PMS MEDİKAL AMBALAJ SANAYİ VE TİCARET LTD. ŞTİ./765
BELGE SAHİBİ KURULUŞUN ADRESİ *ADRESS OF THE LICENCE HOLDER*	KARADUVAR MAH. SERBEST BÖLGE 11. CADDE NO:46 AKDENİZ MERSİN/TÜRKİYE
ÜRETİM YERİ ADI *NAME OF THE MANUFACTURING PLACE*	PMS MEDİKAL AMBALAJ SANAYİ VE TİCARET LTD. ŞTİ.
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)*	14.11.35/2169
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 -- 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

TÜRK STANDARTLARI ENSTİTÜSÜ ADANA BELGELENDİRME MÜDÜRLÜĞÜ TSE

21../03.2014

MEHMET UĞUR ÖZDENİZ
ADANA BELGELENDİRME MÜDÜRÜ

*Bu belge, belgelendirilen ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.

ADANA* ADANA BELGELENDİRME MÜDÜRLÜĞÜÇınarlı 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 * web: * e-mail:

Bu belge hiç bir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz. 1 / 1

Annex 4 | Technical Data Sheet Sterilization Reel

TECHNICAL DATA SHEET

TECHNICAL DATA SHEET

STERILIZATION REEL (FLAT / GUSSETED - 60 gr)

PRODUCT CODE : FL (Flat) - GS (Gusseted)

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

INTENDED USE : PMSSteripack Reels are designed to provide excellent barrier for sterile medical device packaging purposes. 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.
PMSSteripack Reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.

OPERATION CONDITIONS : PMSSteripack reels are used for steam, ethylene oxide, formaldehyde sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE
MEDICAL PAPER	SUBSTANCE	g/m^2	ISO 536	60
	THICKNESS	µm	ISO 534	83
	BENDTSEN POROSITY	ml/min	ISO 5636-3	1000
	AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	375
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	375
	TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	6,4
	TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,4
	WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,1
	WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,1
	BURST STRENGTH	kPa	ISO 2758	350
	TEARING STRENGTH /MD	mN	ISO 1974	600
	TEARING STRENGTH /CD	mN	ISO 1974	650
	WET BURST	kPa	ISO 3689	150
	WATER REPELLENCY	s	EN 868-2 (app.D)	35
	PORE SIZE	µm	EN 868-2 (app.E)	21
	COBB TEST (60 s)	g/m^2	ISO 535	15
	FLUORESCENCE	pts/dm²	EN 868-2 (app.B)	0
	pH: between 5.0 and 8.0 (ISO 6588-2)	Chloride Content < 0,05% (ISO 9197) Sulphate Content < 0,25% (ISO 9198)		
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

PMSSteripack®

PMS MEDİKAL Amb. San. Tic Ltd. Şti
pms@pmsmedikal.com

TECHNICAL DATA SHEET

STERILIZATION REEL (FLAT / GUSSETED - 60 gr)

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	53 ± 5
				PP	40 ± 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 2029	150 ± 5	
	TEAR	G MD	ASTM D 1922	40 ± 5	
		G TD		50 ± 5	
	GLOSS	%	ASTM D 2457	150 ± 5	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
REEL	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (gr /15 mm) (N)		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 the specified color	

	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
INDICATOR	STEAM	Pink	Brown / Black
	EO	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

PACKAGING : PMS Steripack 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 MEDİKAL Amb. San. Tic Ltd. Şti
pms@pmsmedikal.com

Rev.01

Annex 5 | Technical Data Sheet Sterilization Pouch

TECHNICAL DATA SHEET

STERILIZATION POUCH (FLAT / GUSSETED - 60 gr)

TECHNICAL DATA SHEET

PRODUCT CODE : FP (Flat) - GP (Gusseted)

RELATED STANDARDS : PMSSteripack flat and gusseted 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 Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations

INTENDED USE : PMSSteripack Pouches are designed to provide excellent barrier for sterile medical device packaging purposes. 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. PMSSteripack Pouches are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.

OPERATION CONDITIONS : PMSSteripack pouches are used for steam, ethylene oxide sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE
MEDICAL PAPER	SUBSTANCE	g/m^2	ISO 536	60
	THICKNESS	µm	ISO 534	83
	BENDTSEN POROSITY	ml/min	ISO 5636-3	1000
	AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	375
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	375
	TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	6,4
	TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,4
	WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,1
	WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,1
	BURST STRENGTH	kPa	ISO 2758	350
	TEARING STRENGTH /MD	mN	ISO 1974	600
	TEARING STRENGTH /CD	mN	ISO 1974	650
	WET BURST	kPa	ISO 3689	150
	WATER REPELLENCY	s	EN 868-2 (app.D)	35
	PORE SIZE	µm	EN 868-2 (app.E)	21
	COBB TEST (60 s)	g/m^2	ISO 535	15
	FLUORESCENCE	pts/dm^2	EN 868-2 (app.B)	0
	pH: between 5.0 and 8.0 (ISO 6588-2)	Chloride Content < 0,05% (ISO 9197)		
		Sulfate Content < 0,25% (ISO 9198)		
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

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TECHNICAL DATA SHEET

STERILIZATION POUCH (FLAT / GUSSETED - 60 gr)

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	53 ± 5
				PP	40 ± 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 2029	150 ± 5	
	TEAR	G MD	ASTM D 1922	40 ± 5	
		TD		50 ± 5	
	GLOSS	%	ASTM D 2457	150 ± 5	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (gr /15 mm) (N)		3,0 ± 0,5	4,0 ± 0,75
		Top Seal (gr / 5 mm) (N)		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 the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	Pink	Brown / Black
	EO	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

PACKAGING : PMS Steripack flat pouches are packaged 250 pieces in a film package. Each 1000 pieces are packaged in a carton box.

PMS Steripack gusseted pouches are packaged 100 pieces in a film package. Products up to 20 cm width are packaged 1000 pieces in carton box and widers are packaged 500 pieces in carton box.

PMS Steripack®

PMS MEDİKAL Amb. San. Tic Ltd. Şti
pms@pmsmedikal.com

Rev.01

Annex 6 | CE Declaration of Conformity

PMS MEDİKAL AMBALAJ SAN. VE TİC. LTD. ŞTİ.
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

The EU Directives covered by this Declaration

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

The Products Covered by this Declaration

Sterilization Reel
Sterilization Pouch

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 : January 2014

PMS MEDİKAL AMBALAJ SAN. VE TİC. LTD. ŞTİ.
Karaduvar Mah. Serbest Bölge (Free Zone) 11. Cad.
No: 46 33020 Akdeniz/ Mersin, Turkiye
Tel: +90 324 238 7042 | Fax: +90 324 238 6549
Uvay V.D. 730 019 9872
www.pmsmedikal.com

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 7 | Steam Chemical Indicator Test Report

HIGHPOWER
Validation Testing & Lab Services

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

FINAL REPORT

Chemical Indicator Testing Per ISO 11140-1

Client: Taner ERSEN - Quality Assurance Manager
PMS Medikal Ambalaj San. ve Tic. Ltd. Şti.
Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz,
33020 Mersin Turkey

Study No: 1311-562-1 Revision A

Personnel: Sarah Hart – Validation Technician

Test Sample: PMS Medikal Sterilization Pouch Samples FP2128 Lot #3413, 3013, and 0214

Procedure: A warm up cycle was run to ensure functionality. Test samples were processed in an AAMI/ISO compliant Steam resistometer and Dry Heat vessel per Table 1 of ANSI/AAMI/ISO. In order for the test samples to conform to ANSI/AAMI/ISO 11140-1 standards the samples must meet the Acceptable Result criteria in the table below:

Test and Performance Requirement for Steam Process Indicators

Test Environment	Test Time	Test Temperature	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
Saturated Steam (Pass Cycle)	10.0 min ± 5 sec	121°C (+3/0°C)	Unacceptable Result	Acceptable Result
Saturated Steam (Fail Cycle)	3.0 min ± 5 sec	121°C (+3/0°C)	Acceptable Result	Unacceptable Result
Saturated Steam (Pass Cycle)	2.0 min ± 5 sec	134°C (+3/0°C)	Unacceptable Result	Acceptable Result
Saturated Steam (Fail Cycle)	0.5 min ± 5 sec	134°C (+3/0°C)	Acceptable Result	Unacceptable Result
Dry Heat	30.0 min ± 1 min	140°C (+2/0°C)	Acceptable Result	Unacceptable Result

Table 1

Results: The PMS Medikal sterilization pouch samples ran in the pass cycles were markedly different from the samples run in the fail and dry heat cycles.

Page 1 of 2

HIGHPOWER No. 1311-562-1 Revision A
PMS Medikal Ltd. ISO 11140-1 Testing

Testing Results Per ANSI/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	Test Result
Saturated Steam (Pass Cycle)	10.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	3.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Pass Cycle)	2.0 min ± 5 sec	134°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	0.5 min ± 5 sec	134°C (+3/0°C)	Acceptable
Dry Heat	30.0 min ± 1 min	140°C (+2/0°C)	Acceptable

Table 2

Conclusion: Results of testing verify that the PMS Medikal sterilization pouches conform to the ANSI/AAMI/ISO 11140-1 requirements for steam process indicators.

Testing performed by: Sarah Hart **Date:** 6/4/14

Reviewed by: Ken Jacks **Date:** 06-04-14

NOTICE: All protocols and reports are submitted to clients on a confidential basis. Test results are applicable only to the Test Samples that were tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples. HIGHPOWER Validation Testing & Lab Service shall not be liable under any circumstances for any amount in excess of the cost of the test(s) performed.

Page 2 of 2

Annex 8 | EO Chemical Indicator Test Report

HIGHPOWER
Validation Testing & Lab Services

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

FINAL REPORT

Chemical Indicator Testing Per ISO 11140-1

Client: Taner ERSEN - Quality Assurance Manager
PMS Medikal Ambalaj San. ve Tic. Ltd. Şti.
Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz,
33020 Mersin Turkey

Study No: 1311-563 Revision A

Personnel: Alex Belik – Sr. Microbiology Technician

Test Sample: PMS Medikal Sterilization Pouch Samples FP2128 Lot #1613

Procedure: Test samples were processed in an AAMI/ISO compliant EO Gas sterilizer per Table 3 of ANSI/AAMI/ISO. In order for the test samples to conform to ANSI/AAMI/ISO 11140-1 standards the samples must meet the Acceptable Result criteria in the table below:

Test and Performance Requirement for Class 1 process indicators for EO

Test Environment	Test Time	Test Temperature	RH%	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 EO gas	90 min ± 1 min	60°C ± 2°C	≥ 85%	None	Acceptable Result	Unacceptable Result
EO gas Test at:	5 min ± 15 sec	30°C ± 1°C	60 % ± 10% RH	600 mg/L ± 30 mg/L	Acceptable Result	Unacceptable Result
	2 min ± 15 sec	54°C ± 1°C				
EO gas test at:	30 min ± 15 sec	30°C ± 1°C	60% ± 10 % RH	600 mg/L ± 30 mg/L	Unacceptable Result	Acceptable Result
	20 min ± 15 sec	54°C ± 1°C				

Table 1

Results: The PMS Medikal sterilization pouch samples ran in the pass cycles were markedly different from the samples run in the fail cycles.

Page 1 of 2

HIGHPOWER No. 1311-563 Revision A
PMS Medikal Ltd. ISO 11140-1 Testing

Testing Results Per ANSI/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	RH%	Gas Concentration mg/L	Results
Absence of EO gas	90 min ± 1 min	60°C ± 2°C	≥ 85%	None	Acceptable Result
EO gas Test at:	5 min ± 15 sec	30°C ± 1°C	60 % ± 10% RH	600 mg/L ± 30 mg/L	Acceptable Result
	2 min ± 15 sec	54°C ± 1°C			
EO gas test at:	30 min ± 15 sec	30°C ± 1°C	60% ± 10 % RH	600 mg/L ± 30 mg/L	Acceptable Result
	20 min ± 15 sec	54°C ± 1°C			

Table 2

Conclusion: Results of testing verify that the PMS Medikal sterilization pouches conform to the ANSI/AAMI/ISO 11140-1 requirements for EO process indicators.

Testing performed by: Alex Bell **Date:** 6/4/14

Reviewed by: [signature] **Date:** 06-04-14

NOTICE: All protocols and reports are submitted to clients on a confidential basis. Test results are applicable only to the Test Samples that were tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples. HIGHPOWER Validation Testing & Lab Service shall not be liable under any circumstances for any amount in excess of the cost of the test(s) performed.

Page 2 of 2

Annex 9 | FO Chemical Indicator Test Report

HIGHPOWER
Validation Testing & Lab Services

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

FINAL REPORT

Chemical Indicator Testing Per ISO 11140-1

Client: Taner ERSEN - Quality Assurance Manager
PMS Medikal Ambalaj San. ve Tic. Ltd. Şti.
Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz,
33020 Mersin Turkey

Study No: 1311-564 Revision A

Personnel: Alex Belik – Sr. Microbiology Technician

Test Sample: PMS Medikal Sterilization Pouch Samples FP2128 Lot #1613

Procedure: Test samples were processed in Formaldehyde per Table 5 of ANSI/AAMI/ISO. In order for the test samples to conform to ANSI/AAMI/ISO 11140-1 standards the samples must meet the Acceptable Result criteria in the table below:

Test and Performance Requirement for Class 1 process indicators for FORM

Test Environment	Test Time	Test Temperature	Gas Concentration mol/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 formaldehyde	90 min ± 1 min	80°C ± 2°C	None	Acceptable Result	Unacceptable Result
Formaldehyde	20 s ± 5 s	60°C ± 0.5°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result	Unacceptable Result
Formaldehyde	15 min ± 15 s	70°C ± 2°C	1.0 mol/L ± 0.01 mol/L	Unacceptable Result	Acceptable Result

Table 1

Results: The PMS Medikal sterilization pouch samples ran in the pass cycles were markedly different from the samples run in the fail cycles.

Page 1 of 2

HIGHPOWER No. 1311-564 Revision A
PMS Medikal Ltd. ISO 11140-1 Testing

Testing Results Per Ansi/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	Gas Concentration mol/L	Results
Absence of formaldehyde	90 min ± 1 min	80°C ± 2°C	None	Acceptable Result
Formaldehyde:	20 s ± 5 s	60°C ± 0.5°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result
Formaldehyde	15 min ± 15 sec	70°C ± 2°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result

Table 2

Conclusion: Results of testing verify that the PMS Medikal sterilization pouches conform to the ANSI/AAMI/ISO 11140-1 requirements for FORM process indicators.

Testing performed by: Alex Bold **Date:** 6/4/14

Reviewed by: [signature] **Date:** 06-04-14

NOTICE: All protocols and reports are submitted to clients on a confidential basis. Test results are applicable only to the Test Samples that were tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples. HIGHPOWER Validation Testing & Lab Service shall not be liable under any circumstances for any amount in excess of the cost of the test(s) performed.

Page 2 of 2

Annex 10 | Bioburden Test Report FL10200

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-14-764 Request No	**BİYOLOJİK YÜK DENEY RAPORU** BIOBURDEN TEST REPORT	TÜRKAK Test TS EN ISO/IEC 17025 AB-0052-T
Teklif No: TLF-14-188 Tender No		AB-0052-T
Kabul Tarihi:24.03.2014 Receiving Date		M14-427
Test Başlangıç Tarihi:27.03.2014 Test Initiation Date:		08.04.2014
Test Bitiş Tarihi:05.04.2014 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

Bu testin hedefi ürün üzerindeki biyolojik yükü tespit etmektir.
The target of the test is to control bioburden of proucts

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

ISO11737-1 standardında tanımlı olan geri kazanım metodu uygulandı.
Microorganism recovery methods described in the ISO113737-1 standard have been applied.

Kullanılan TSA besiyeri bakteri üremesi için 30-35 C°'de 3 gün, mantar üremesi için 20-25°C'de 5 gün inkübe edildi. İnkübasyon sonrası koloni sayımı gerçekleşti. Bilinen geri kazanım faktörü ortalama mikroorganizma sayısı ile çarpılarak toplam mikrooganizma sayısı belirlendi.
TSA media used has been incubated in (to promote bacteria growth) at 30-35°C for 3 days and at 20 -25°C(to promote yeast/molds) for 5 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: 2006 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

Sterilizasyon Rulosu Düz(FL 10200)
N14-1328

NA: Uygulanamaz/Not applicable 1 / 3 23.12.2011/ 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-427
08.04.2014

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

2 Adet

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 15-23 °C
Nem / Humidity: %35-60
Basınç Pressure: 0.02-0.08 inch H2O

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not used

❖ **NUMUNE ORANSAL PARÇASI/** SIP

NA

❖ **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	16	0	16

Ortalama mikroorganizma sayısı x düzeltme faktörü = 16 x 1,84 ≅ 29 kob / numune
Mean microbial count x correction factor = 16 x 1,84 ≅ 29 cfu / sample

Anaerob bakteri sayısı :11
Number of anaerobic bacteria :11

Bakteri Koloni Morfolojisi Colony Morphology of Bacteria	Bakteri Gram Boyama Sonuçları Result of Bacteria Gram Stain
Aerobik Bakteri / Aerobic Bacteria	
Krem dalgalı kenerli	(+) kok
Anaerob Bakteri / Anaerobic Bacteria	
Krem yuvarlak	(+) kok

❖ **LİMİTLER/** LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ **ÖLÇÜM BELİRSİZLİĞİ/** MEASUREMENT UNCERTAINITY

Yoktur / Not present

❖ **SAPMALAR/** DEVIATIONS

NA

NA: Uygulanamaz/Not applicable 2 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-427
08.04.2014

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Mert ÜNSAL BİYOLOG		08.04.14
Laboratuar Onay / Laboratory Approval:	Aysel YILDIRIM KİMYAGER		08.04.14
Kalite Onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER		08.04.14
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.
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NA: Uygulanamaz/Not applicable 3 / 3 23.12.2011 / 270118-F06-03

Annex 11 | Bioburden Test Report GS15100

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-14-764 Request No	**BİYOLOJİK YÜK DENEY RAPORU** BIOBURDEN TEST REPORT	TÜRKAK Test TS EN ISO/IEC 17025 AB-0052-T
Teklif No: TLF-14-188 Tender No		AB-0052-T
Kabul Tarihi:24.03.2014 Receiving Date		M14-428
Test Başlangıç Tarihi:27.03.2014 Test Initiation Date:		08.04.2014
Test Bitiş Tarihi:05.04.2014 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

Bu testin hedefi ürün üzerindeki biyolojik yükü tespit etmektir.
The target of the test is to control bioburden of proucts

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

ISO11737-1 standardında tanımlı olan geri kazanım metodu uygulandı.
Microorganism recovery methods described in the ISO113737-1 standard have been applied.

Kullanılan TSA besiyeri bakteri üremesi için 30-35 C°'de 3 gün, mantar üremesi için 20-25°C'de 5 gün inkübe edildi. İnkübasyon sonrası koloni sayımı gerçekleşti. Bilinen geri kazanım faktörü ortalama mikroorganizma sayısı ile çarpılarak toplam mikrooganizma sayısı belirlendi.
TSA media used has been incubated in (to promote bacteria growth) at 30-35°C for 3 days and at 20 -25°C(to promote yeast/molds) for 5 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: 2006 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

Sterilizasyon Rulosu Körüklü(GS 15100)
N14-1329

NA: Uygulanamaz/Not applicable 1 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-428
08.04.2014

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

2 Adet

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 15-23 °C
Nem / Humidity: %35-60
Basınç Pressure: 0.02-0.08 inch H2O

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır / Not used

❖ **NUMUNE ORANSAL PARÇASI/** SIP

NA

❖ **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	15	0	15

Ortalama mikroorganizma sayısı x düzeltme faktörü = 15 x 1,84 ≅ 28 kob / numune
Mean microbial count x correction factor = 15 x 1,84 ≅ 28 cfu / sample

Anaerob bakteri sayısı :0
Number of anaerobic bacteria :0

Bakteri Koloni Morfolojisi Colony Morphology of Bacteria	Bakteri Gram Boyama Sonuçları Result of Bacteria Gram Stain
Aerobik Bakteri / Aerobic Bacteria	
Krem yuvarlak	(+) kok

❖ **LİMİTLER/** LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ **ÖLÇÜM BELİRSİZLİĞİ/** MEASUREMENT UNCERTAINITY

Yoktur / Not present

❖ **SAPMALAR/** DEVIATIONS

NA

NA: Uygulanamaz/Not applicable 2 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-428
08.04.2014

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Mert ÜNSAL BİYOLOG		08.04.14
Laboratuar Onay / Laboratory Approval:	Aysel YILDIRIM KİMYAGER		08.04.14
Kalite Onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER		08.04.14
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.
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NA: Uygulanamaz/Not applicable 3 / 3 23.12.2011 / 270118-F06-03

Annex 12 | Bioburden Test Report FP15195

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
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labinfo@bicakcilar.com

Talep No: TLP-14-764 Request No	**BİYOLOJİK YÜK DENEY RAPORU** BIOBURDEN TEST REPORT
Teklif No: TLF-14-188 Tender No	
Kabul Tarihi:24.03.2014 Receiving Date	
Test Başlangıç Tarihi:27.03.2014 Test Initiation Date:	
Test Bitiş Tarihi:05.04.2014 Test Final Date:	

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

AB-0052-T
M14-429
08.04.2014

❖ **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

Bu testin hedefi ürün üzerindeki biyolojik yükü tespit etmektir.
The target of the test is to control bioburden of proucts

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

ISO11737-1 standardında tanımlı olan geri kazanım metodu uygulandı.
Microorganism recovery methods described in the ISO113737-1 standard have been applied.

Kullanılan TSA besiyeri bakteri üremesi için 30-35 C°'de 3 gün, mantar üremesi için 20-25°C'de 5 gün inkübe edildi. İnkübasyon sonrası koloni sayımı gerçekleşti. Bilinen geri kazanım faktörü ortalama mikroorganizma sayısı ile çarpılarak toplam mikrooganizma sayısı belirlendi.
TSA media used has been incubated in (to promote bacteria growth) at 30-35°C for 3 days and at 20 -25°C(to promote yeast/molds) for 5 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: 2006 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

Sterilizasyon Poşeti Düz FP 150X195mm
N14-1330

NA: Uygulanamaz/Not applicable 1 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-429
08.04.2014

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

2 Adet

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 15-23 °C
Nem / Humidity: %35-60
Basınç Pressure: 0.02-0.08 inch H2O

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır./ Not used

❖ **NUMUNE ORANSAL PARÇASI/** SIP

NA

❖ **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	10	0	10

Ortalama mikroorganizma sayısı x düzeltme faktörü = 10 x 1,84 ≅ 18 kob / numune
Mean microbial count x correction factor = 10 x 1,84 ≅ 18 cfu / sample

Anaerob bakteri sayısı :0
Number of anaerobic bacteria :0

Bakteri Koloni Morfolojisi Colony Morphology of Bacteria	Bakteri Gram Boyama Sonuçları Result of Bacteria Gram Stain
Aerobik Bakteri / Aerobic Bacteria	
Sarı yuvarlak	(+) kok

❖ **LİMİTLER/** LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ **ÖLÇÜM BELİRSİZLİĞİ/** MEASUREMENT UNCERTAINITY

Yoktur / Not present

❖ **SAPMALAR/** DEVIATIONS

NA

NA: Uygulanamaz/Not applicable 2 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M14-429
08.04.2014

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Mert ÜNSAL BİYOLOG	.....	08.04.14
Laboratuar Onay / Laboratory Approval:	Aysel YILDIRIM KİMYAGER	.....	08.04.14
Kalite Onay / Quality Approval:	Özenç EFE ÖZTÜRK KİMYAGER	.....	08.04.14
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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NA: Uygulanamaz/Not applicable 3 / 3 23.12.2011 / 270118-F06-03

Annex 13 | Bioburden Test Report GP1030

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-13-1855 Request No	**BİYOLOJİK YÜK DENEY RAPORU** BIOBURDEN TEST REPORT	TÜRKAK Test TS EN ISO/IEC 17025 AB-0052-T
Teklif No:TLF-13-502rev01 Tender No		AB-0052-T
Kabul Tarihi:24.09.2013 Receiving Date		M13-728
Test Başlangıç Tarihi:25.09.2013 Test Initiation Date:		07.10.2013
Test Bitiş Tarihi:03.10.2013 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

Bu testin hedefi ürün üzerindeki biyolojik yükü tespit etmektir.
The target of the test is to control bioburden of proucts

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

ISO11737-1 standardında tanımlı olan geri kazanım metodu uygulandı.
Microorganism recovery methods described in the ISO113737-1 standard have been applied.

Kullanılan TSA besiyeri bakteri üremesi için 30-35 C°'de 3 gün, mantar üremesi için 20-25°C'de 5 gün inkübe edildi. İnkübasyon sonrası koloni sayımı gerçekleşti. Bilinen geri kazanım faktörü ortalama mikroorganizma sayısı ile çarpılarak toplam mikrooganizma sayısı belirlendi.
TSA media used has been incubated in (to promote bacteria growth) at 30-35°C for 3 days and at 20 -25°C(to promote yeast/molds) for 5 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: 2006 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

Sterilizasyon Rulosu (Körüklü GP)100*300mm
Talep No:109
N13-3199

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

NA: Uygulanamaz/Not applicable 1 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M13-728
07.10.2013

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 15-23 °C
Nem / Humidity: %35-60
Basınç Pressure: 0.02-0.08 inch H2O

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır / Not used

❖ **NUMUNE ORANSAL PARÇASI/** SIP

NA

❖ **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	26	0	26

Ortalama mikroorganizma sayısı x düzeltme faktörü = 26 x 1,84≅ 48 kob / numune
Mean microbial count x correction factor =26 x 1,84 ≅ 48 cfu / sample

Anaerob bakteri sayısı :32
Number of anaerobic bacteria :32

Bakteri Koloni Morfolojisi Colony Morphology of Bacteria	Bakteri Gram Boyama Sonuçları Result of Bacteria Gram Stain
Aerobik Bakteri / Aerobic Bacteria	
Krem dalgalı kenarlı	(+) basil
Anaerob Bakteri / Anaerobic Bacteria	
Krem yuvarlak	(+) kok

❖ **LİMİTLER/** LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ **ÖLÇÜM BELİRSİZLİĞİ/** MEASUREMENT UNCERTAINITY

Yoktur / Not present

❖ **SAPMALAR/** DEVIATIONS

NA

NA: Uygulanamaz/Not applicable 2 / 3 23.12.2011 / 270118-F06-03

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

AB-0052-T
M13-728
07.10.2013

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Mert ÜNSAL BİYOLOG	.....	07.10.13
Onay / Approret by	Aysel YILDIRIM KİMYAGER	.....	07.10.13
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.
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Testing reports without signature and seal are not valid

NA: Uygulanamaz/Not applicable 3 / 3 23.12.2011 / 270118-F06-03

Annex 14 | 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. 1311-568 Revision A

MICROBIAL AEROSOL CHALLENGE OF THE PMS MEDIKAL STERILIZATION POUCHES STEAM STERILIZATION

Prepared for:

PMS Medikal Ambalaj San. ve Tic. Ltd. Şti.
Karaduvar Mah. Serbest Bölge 11. Cadde No: 46, Akdeniz,
33020 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

6/5/14
Date

FINAL REPORT
HIGHPOWER Study No. 1311-568 Revision A
PMS Medikal
Microbial Aerosol Challenge

Study No.:	1311-568 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
Report prepared By:	Joe Steinert- Validation Technicion
Study Personnel:	Joe Steinert – Validation Technician, Laboratory Services.
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. ANSI/AAMI ST8:2008; Hospital Steam Sterilizers
5. AAMI TIR12:2010 Designing testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
6. ANSI/AAMI ST79:2010 & A1:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
7. HIGHPOWER Internal SOP's
8. LSOP 072 Aerosol Challenge Procedure

FINAL REPORT
HIGHPOWER Study No. 1311-568 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 Steam sterilization 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 Steam sterilizer HIGHPOWER Equipment # 500
3.3 Stainless Steel Coupons
3.4 Pouch Divider
3.5 SPSmedical STEAM*Plus*™ Class 5 Integrators: Lot # 348
3.6 HEPA Laminar Flow Hood: HIGHPOWER Equipment # 045
  3.6.1 Test Organism: *Bacillus atrophaeus* 9372
  3.6.2 Aerosol Suspension: Batch # 131125 from BT207
3.7 Test Organism: *Geobacillus stearothermophilus* 7953
  3.7.1 BI Spore Strips: Lot # RU39
  3.7.2 Low Colony Spore Strips: Lot # LA12
3.8 Microbiological Culture Media
  3.8.1 Tryptic Soy Broth (TSB): Batch # 131211-1
  3.8.2 Tryptic Soy Agar (TSA): Batch # 131125-1, 131210-1
3.9 USP Extraction Fluid: Batch # 131203-1
3.10 Incubator monitored and logged daily
  3.10.1 Calibrated at 30 - 37°C: HIGHPOWER Equipment # 253
  3.10.2 Calibrated at 55 - 60°C: HIGHPOWER Equipment # 254
3.11 Sterile Lab Transfer Equipment
3.12 Sterile Lab Transfer Attire
3.13 N.I.S.T. Traceable Timer: HIGHPOWER Equipment # 568, 632

Page 3 of 7

FINAL REPORT
HIGHPOWER Study No. 1311-568 Revision A
PMS Medikal
Microbial Aerosol Challenge

4.0 PRE-VACUUM STEAM STERILIZATION CYCLE DESCRIPTION:

Temperature:	270°F (132°C)
Time:	4.0 minutes
Dry Time:	20.0 minutes

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 integrator and one (1) biological indicator: See Figure 1.

6.3 The pouches were heat sealed and labeled.

6.4 The pouches were placed in an otherwise empty sterilizer chamber, the door was closed and the pouches were processed in the Steam sterilization cycle stated in Section 4.0.

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 ~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 Integrators were observed for adequate steam penetration.

6.17 The cycle printout tapes were verified.

6.18 All results were recorded: See Table 2.

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.

FINAL REPORT
HIGHPOWER Study No. 1311-568 Revision A
PMS Medikal
Microbial Aerosol Challenge

8.0 RESULTS:

8.1 The test sample coupons demonstrated no growth following incubation (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 rates to be 752 CFU/cm^2.

9.0 CONCLUSION

Based on the results of testing the PMS Medikal 210 X 280mm sterilization pouches are an effective microbial barrier following a Steam sterilization cycle, and when subjected to an aerosol challenge.

BILL OF MATERIALS

Quantity	DESCRIPTION	Lot #
3	PMS Medikal Sterilization Pouches 210 X 280 mm	1613

TABLE 1

Page 5 of 7

FINAL REPORT
HIGHPOWER Study No. 1311-568 Revision A
PMS Medikal
Microbial Aerosol Challenge

SAMPLE LOAD CONFIGURATION
TOP VIEW OF POUCH

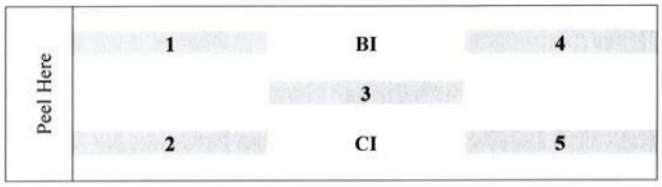
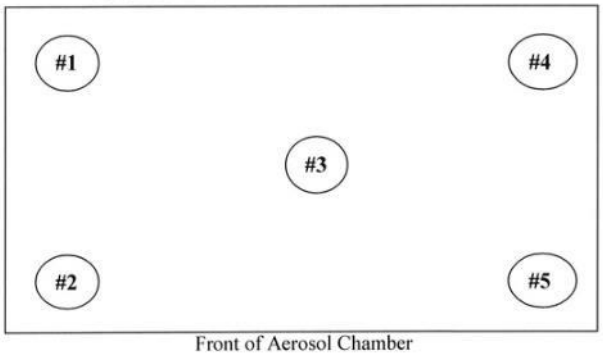


FIGURE 1

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

GAUZE PLACEMENT IN AEROSOL CHAMBER



Front of Aerosol Chamber

FIGURE 2

Page 6 of 7

FINAL REPORT
HIGHPOWER Study No. 1311-568 Revision A
PMS Medikal
Microbial Aerosol Challenge

TEST RESULTS

Sample ID		Pouch # 1	Pouch # 2	Pouch # 3
LOT: 1613	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 – RU39		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

Page 7 of 7