VIGILENZ® SHOP PACKET - OPERATION (MESH) REF RM6110SP ODR. QTY 120 RS 1 BOX (6PCS) ORDER NO. A060 6/BXS VMS (MALAYSIA) ITEM CODE 13000857 PACK SIZE CUSTOMER A20802 LOT NO: MFG DATE 10-Jan-22 ITEM DESCRIPTION Vigimesh SP 6 x 11cm 10-Jan-22 2027-01 ISSUED DATE EXP DATE NAME: RATNASEGARAN NAME: NUR SHAHIRA IO/VMS/060122/01 VERIFIED BY INT. ORDER PREPARED BY DATE: 10/01/2022 DATE: 10/01/2022 OUTPUT REJECT IPQC START QTY OPERATOR REMARKS PROCESS APPROVAL PCS PCS LASER CUTTING They 1.308 TIME START : RUSDI STO POSHNI NIL 126 126 01 2 2 MA DATE: 3-00 pm 3.00 pm TIME COMPLETE: 01-22 DATE ULTRASONIC WASH Hoshin 3:25 PM TIME START : 1 Canjano 3-30 pm 01-22 MA DATE Nil 126 126 (790) 3:30 PM TIME COMPLETE: 11/1/23 0 1 -2 2 DATE DRYING Roshni 4:00 pm TIME START: Caujan a ND 0 1 2 2 Nil DATE: 8-309M 126 126 (798) EME COMPLETE : 12/01/22 01-22 E SLIT MESH ON SUPPORT CARD 1:00 PM vikneswary TIME START : Roshi 2 2 NI 0 1 DATE : 126 126 NA 2.00 pm (1094) 2:00 Pm TIME COMPLETE : 0 1 2 2 18/01/2022 DATE SLOT INTO POUCH 2:00 Pm Poshni TIME START: virneswary 0 1 -2 2 pil DATE NO 126 3-00pm 126 :00 Pm TIME COMPLETE: (1094) 15/01/2022 0 2 2 POUCH SEALING tera :30 TIME START : Nil touvill NA 01 2 2 126 126 DATE (932) 4:00 TIME COMPLETE : 24/01/22 2 2 0 1 DATE POUCH LABELLING Tasho 2:30 TIME START: (Hoving 4:00 126 Nil DATE: 126 1089) MIA TIME COMPLETE: 24/01/22 19 0 1 2 PACKING & FINAL CONTROL F19 (932) Poshin TIME START : 1:00 Pm _ 0 1 _ 2 2 126 Nil NA DATE: 126 2.30 pm Netra (1103) 2:30 PM TIME COMPLETE : 20/01/22 22 Kali (1078) -01 29 DATE SHRINK WRAP 10:30 di m Nurin FACU TIME START: 8/07 20 20 (1054)DATE . M 24/1/22 Box TIME COMPLETE: BUX Rabin (1088) 24 0 1 DATE: CARTON PACK Nurin 20 HERDI TIME START : 10:30 am 20 22 HI 0 1 (1053)DATE: 24/1/12 Box 24/01/22 BOX TIME COMPLETE : DATE: 22 Checked by (PR), Approved by (QA), STERILIZATION ЕТО Released by (QC) 07 STERILIZATION DATE: Signature: Signature: Signature Royam-a ahman STERILIZATION BATCH CAMENSE CHAM ETO 220143 MARTINI NUMBER: 4/2/2022 FINAL SHIPMENT DATE Designation : QC pepi Mesh taken from Semi-Finish Mesh Shop Packet need to record below information for traceability; SHIPMENT QUANTITY Date: 37/01/2022 JOKE 20/04 PCS / CTNS: 1) Semi-finish Mesh Lot No. Stamp (S.E.A) SO COMPLETE COMPLETE/PARTIAL: PARTIAL

1 of 2

2) Mesh Supplier Lot No.:

3) Mesh Roll No.

1 box

RETAIN SAMPLE :

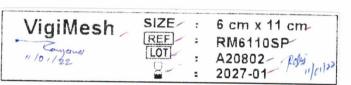
VMD SAMPLE:



LABEL PRINTING PROCESS

PROCESS	START QTY PCS	OUTPUT PCS	OPERATOR	REJECT PCS	IPQC APPROVAL	REMARKS
PRINTING POUCH LABEL TIME START: DATE: TIME COMPLETE: DATE:	3		N/A			
PRINTING BOX LABEL TIME START: DATE: TIME COMPLETE: DATE:	Heiss.		N/A			_

LABEL APPROVAL





Small Pore Standard Weight

SIZE: 6cm x 11cm



REF RM6110SP

LOT A20802 ~

≥ 2027-01 ✓

MDA NO . GC1209349316



Manufactured by: VIGILENZ MEDICAL DEVICES Sdn. Bhd. 308 b, Penang Science Park, 14100 Penang, Malaysia.

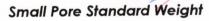


EC REP OBELIS S.A BD. GENERAL WAHIS 53 1030 BRUSSELS, BELGIUM

STERILE EO A S

Polypropylene Mesh. Knitted. Non-Absorbable





QTY: 6 Pcs

REF RM6110SP

LOT A20802

2027-01/

MDA NO . GC1209349316



SIZE: 6cm x 11cm delson

Manufactured by:

VIGILENZ MEDICAL DEVICES Sdn. Bhd.

308 b, Penang Science Park, 14100 Penang, Malaysia.





LABIEL PRINTING CHECKLIST	- VIGIMESH				
DESCRIPTION	Vigimesh SP 6 x 11cm				
REF	RM6110SP			INNER POUCH	BOX LABEL
LOT NO	A20802	DATE PF		15/1/2022	15/1/4002
EXP. DATE	2027-01	QTY PRI	NTED (PCS)	127	22
COUNTRY	VMS (MALAYSIA)	PRINTE	BY	RUSD1 857	PASO 877
ORDER QTY	120 + 6	REMARK			
**		INNE	RPOUCH	ВОХ	LABEL
	SPECS	OK	NOT OK	OK	NOT OK
a. LABEL SELECTION	VIGIMESH				
o. REF NO	RM6110SP				15/0
c. MESH SIZE	6 x 11cm				
d. CE MARK	YES	/			
e. LOT NO	A20802				
E EXP DATE	2027-01				
SPECIAL REQUIREMENT	NIL				
	CHECKED BY	15/61/2022	el		
	(QC / IPQC) Date :	15/61/2022		Doc	. No : PR-LP00 Rev:

THE LOUIS

Trans. Committee

VIGILENZ®

IN-PROCESS INSPECTION RECORD – SURGICAL HERNIA MESH

Doc. No.	QC-IP005
Rev.	01

Reference / Lot No.	RM61105P 1A20802
Order Quantity	120

A) LASER CUTTING

	Sampling Sai			ample AQL			Results	
No.	Inspection Criteria	Details	Size	Accept	Reject	Accept	Reject	(Pass / Fail)
1.	Mesh free from burr	54,0.4	32	0	t	39	0	pass
2.	No contamination	Sy, 0.4	22	0	1	30	0	puss
3.	No burn marks	Sy , 0.4	32	<i>0</i>	1	y	0	pass
4.	Edges are well sealed	54, 0.4	30	0	1	32	0	puss
5.	No warping of mesh	54,0.4	32	0	1 2	32	0	pass
6.	Dimension (Tolerance: +0.2cm/ -0cm)	S4, 0.454	43	0	1	3)	0	pass

B) ULTRASONIC WASHING

Sampling Solution not expired		No contamination trapped in the pore	No damage, warping or tear of mesh	Test Disposition (Pass / Fail)	
SIr		~	V	pass	
1/5		V	/	12985	
215	./	V	/	Pass	
1/5		.,		pass	
4/5	.,	1		pass	
7/0		V		pass	

C) DRYING

Sampling No presence of moisture		No discoloration	No damage or warping of mesh	Test Disposition (Pass / Fail)	
51-	1/	V		pas	
3/5	~	V		pass	
7/5	./	/	/	pass	
2/5		,	/	pass	
3/5			/	pass	
4/5		/	/	Pass	

D) SLIT MESH ON SUPPORT CARD

Correct Position of the Inserted Mesh	No Contamination on Mesh	No Contamination on Support Card	Test Disposition (Pass / Fail)	
1.7	~	V	pass	
	V	V	pass	
	V	V	pass	
./	,	V	pass	
	./	V	pass	
/	/	/	Pass	
		Collect 1 osition of	Correct rosition of	

VIGILENZ®	V	IG	II	FN	JZ®
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IN-PROCESS INSPECTION RECORD – SURGICAL HERNIA MESH

Doc. No.	QC-IP005
Rev.	01

E) SLOT INTO POUCH

Sampling	Correct Position of the Support Card	No tear, deformed, damage or contamination on pouch	Test Disposition (Pass / Fail)	
5/5	V	V	pass	
1/5	J		paus	
2/5	✓		pass	
3/5	~	_	pass	
4/5	✓	V	pass	
5/5	~	/	pass	

F) POUCH SEALING

	Visual Ins	spection	Seal Integrity (first 4 p			pieces)		Test
Sampling	Proper and	No melting	Seal strength (min 0.50 kgf) 1 2 Average		Peel test	Seal width (9±1mm)	Disposition	
N.	consistent sealing seam	defects			1 1 1 1	(continuous sealing)	()=111111)	(Pass / Fail)
414	2	/	1.35	1,77	1.56 kg A		-	Pass
1/5		_	Instrument Used		and the second	NA NE-	Pass	
2/5	/	V	1.	iisti uiiieiit	Useu			pass
3/5	V (-					V	pass
4/5		~	00-	92,00	-02		V	Pass
5/5	_	~	1				~	Pass

G) POUCH LABELLING

* Inspection criteria as per Control Plan QCCP-04.

Sampling	Lot No. and Ref No. on Tabel corresponds to shop packet	Correct orientation of labeling on the pouch	Test Disposition (Pass / Fail)
5/5	~	V	Dass
1/5	~	L	Dass
2/5	~	٥ ,	Pags
3/5	~	V	Pags
415	<u></u>	V	Pass
5/5	~		Poss

REMARKS: _	N/s		
	21		

Inspected By:

Approved By:

Name

Proving

Name

Date

Approved By:

Name

Date

12 | 07 | 2622

VIGILENZ®

FINAL CONTROL TEST REPORT – HERNIA MESH

QC-FC002	01
Doc. No.	Rev

Reference Code	Rm 6110SD	Lot. No.	A 20802		
Item Description	viginesh sp 6× 11 cm	Quantity Produced	126	Retain Sample	160%

betails size Accept Reject Accept Reject Reject Reject abel) 1, 0.15 80 0 1 80 0 1, 0.15 80 0 1 80 0 1, 0.15 80 0 1 80 0 s inside 1, 1.0 13 0 1 1 0 ration 1, 1.0 13 0 1 1 0 0 ration 1, 1.0 13 0 1 13 0 0 0 ration 1, 1.0 13 0 1 13 0 0 0 0 0	;	Inspection Criteria	Sampling	Sample	AQL	T	Res	Results	Status De	Troil
1, 0.15 80 0 1 80 1, 0.15	No.		Details	size	Accept	Reject	Accept	Reject	Status (Fass / Fail)	SS / Fall)
and legible 1, 0.15 80 0 1 80 g orientation 1, 0.15 80 1 80 sorientation 1, 1.0 13 0 1 13 ters or particles inside ters or particles inside 1, 1.0 13 0 1 13 amage / discoloration 1, 1.0 13 0 1 13 ize 1, 0.15 80 1 80	-:	Labeling should correspond to shop packet (Outer Pouch & Box Label)	1, 0.15	&	0	-	8	0	P0.88	88
g orientation 1, 0.15 80 0 1 80 L, 1.0 13 0 1 13 ters or particles inside 1, 1.0 13 0 1 13 amage / discoloration 1, 1.0 13 0 1 13 ize 1, 0.15 80 0 1 80		Printing is clear and legible	1, 0.15	80	0	~	08	0	9	paes
ters or particles inside		Correct labeling orientation	I, 0.15	%	0	-	80	0	bo	pass
1, j.0 13 0 1 13 1, 1.0 13 0 1 13 1, 0.15 80 0 1 80		Proper Sealing	1, 1.0	13	0	8	13	0	DO	pass
1,71.0 13 0 1 13 13 14 15 15 15 15 15 15 15 15 15 15 15 15 15		No foreign matters or particles inside package	1, 1.0	13	0	-	13	0))	Spad
1, 0.15 80 0 1		No warping / damage / discoloration	1,1.0	13	0	•	13	.0	pd	pase
		Correct Pack Size	I, 0.15	.80	0	*	80	0	b	paes

* P= Pass / F=Fail

REMARKS:

Inspected By : Row

Name Date

Verified By : 34 Park R. Name : MAR. Date : 25

NARTINI 22/01/2022

			Doc. No.
VIGII	IGH ENZ®	RAV TATERIAL LOADING FORM (RMLF)	Rev.
DATE .	11/01/2022	SHOP PACKET QTY (pcs) :	120
·			CATONA TARA SAME
. JJG	RM6110SP	CUSTOMER :	VMS (MALATSIA)
· ·			
			10/CC1070/3/CVC1

/				RECEIVED BY		en el me
RS	-			RE		-
		VMS (MALAYSIA)	IO/VMS/060122/01		CONSUMPTION	2.65
120				QUANTITY (pcs)	ISSUED	2.65
The state of the s	SHOP PACKET Q11 (pcs)	OMER :			REQUIRED	2.65
d	SHOP	CUSTOMER	LO NO.		MOO	pcs
					LOT NO.	M020210601
					DESCRIPTION 2	VIGIMESH SP 6 X 11 cm
	11/01/2022	RM6110SP	A20802		ITEM DESCRIPTION 1	Surgical Mesh Polypropylene (PPKM 602, Standard)
	DATE :	REF	OUTOI		NO. SYSTEM CODE	1 V0100002

(2	PRODUCT	(2) PRODUCT PACKAGING				(3)
ON	SYSTEM CODE	ITEM DESCRIPTION I	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	ž
-	P0100439	Support Card For Vigimesh - Sizæ 160mm x 165mm, Material: Arteard 230gm, 1 Color Printing	P01L200201	126	e Canjana	
2	V0100024	181 mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE	P02C200201	126	· Caujano	2
6	V0100016	VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE	P108200201	20 + 1	onoho,	8
4	P0100507	IF-SB-CNEN-LH Rev: 06, Size: 110mm x 110mm IFU Vigimesh	P070200201	20 + 1	, Caujano	9
S	V0100023	BL00003 - Printed Vigimesh Pouch Label, Size I 30mm x 60mm, Material: MP (New revision)	L120210701	147	· Cayano	Z
9	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210502	20	· (aujang	
7		#N/A				

100	ER WRAPPING A	OVER WRAPPING AND CARTON PACK			
ON	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
_	P0100371	Corngated Carton Box (Part No. ZV07VIGILENZC) - Size. 595 x 375 x 365mm, Printing Plate. P12697	P100210901	/	meluly
2		#N/A			
ю		#N/A			
) SP) SPECIAL REQUIREMENT	EMENT			
ON ON	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
-	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour. Red (2 layers)		- 42	
7		#N/A			

ISSUED BY (MM):

Signature: Name:

11/01/2022 LOVIN

Date:

VERIFIED BY (PR): Signature:

Name: Date:

Peel test (aprs) passed on 19/01/2002

VIGILENZ®

PRODUCT RELEASE TEST REPORT – HERNIA MESH

E

QC-PC004 04 Doc. No. Rev.

	Maymor	Walmosh Co Co won	Reference No.		Rm61105p	Date of Inspection	n 26/01/2023	660
Item Description	The state of the s	ask of new	Lot No.		A30803	Sample Size	2 005	
Sterilization Process	S E10		Sterilization Batch No.	Batch No.	FT0 330 143	Sterilization Date	19/01/23	25
		Visual Inspection	tion		í	Phy	Physical Inspection	uc
Correct Labeling (Outer Pouch &	Packing Integrity	Edges Are Well Sealed	Free from Warping and Damage of Mesh	No Discoloration of Mesh	ion Tolerance: (+0.2cm/-0cm)	Pouch	Seal Strength (after ETO Steriliz Min 0.50 kgf Instrument used: \(\int \epsilon^{\cup-63}, \int \epsilon^{\cup-9}\)	O Sterilization)
DOA LADOL)			0			1	2	Average
>	>	>)	1126	6.3cm x 11.2cm	hh-1	66.0	Spree-1

 $\sqrt{}$ = Pass X= Fail

RELEASE CONCLUSION:

ON-HOLD

NA REMARKS:

KOSHME Inspected By: Post Name

6601/10/26

Date

Approved By:

Name Date

25/61/2022 4 4 KTIN !