

## SHOP PACKET - OPERATION (MESH)

REF	RM6110SP	ODR. QTY	120	RS 1 BOX (6PCS)	ORDER NO.	A060
ITEM CODE	13000857	PACK SIZE	6/BXS	CUSTOMER	VMS (MALAYSIA)	
ITEM DESCRIPTION	Vigimesh SP 6 x 11cm	LOT NO:	A20802	MFG DATE	10-Jan-22	
		ISSUED DATE	10-Jan-22	EXP DATE	2027-01	
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN	INT. ORDER	IO/VMS/060122/01	
	DATE : 10/01/2022		DATE : 10/01/2022			

PROCESS	START QTY	OUTPUT PCS	REJECT PCS	OPERATOR	IPQC APPROVAL	REMARKS
<b>LASER CUTTING</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	RUSDI ST	Rosni 3:00 pm 11/01/22	N/A
<b>ULTRASONIC WASH</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Kanjana (790)	Rosni 3:30 pm 11/01/22	N/A
<b>DRYING</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Kanjana (790)	Rosni 8:30 am 12/01/22	NA
<b>SLIT MESH ON SUPPORT CARD</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Vikneswary (1094)	Rosni 2:00 pm 15/01/2022	NA
<b>SLOT INTO POUCH</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Vikneswary (1094)	Rosni 3:00 pm 15/01/2022	NA
<b>POUCH SEALING</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Erg (932)	Rosni 24/01/22	N/A
<b>POUCH LABELLING</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Tasha (1089)	Rosni 24/01/22	N/A
<b>PACKING &amp; FINAL CONTROL</b>						
TIME START : DATE : TIME COMPLETE : DATE :	126	126	Nil	Erg (932) Netra (1103) Kali (1078)	Rosni 2:30 pm 20/01/22	NA
<b>SHRINK WRAP</b>						
TIME START : DATE : TIME COMPLETE : DATE :	20 BOX	20 Box	Nil	FACU (1054) Rabin (1088)	Nurin 24/1/22	8/0
<b>CARTON PACK</b>						
TIME START : DATE : TIME COMPLETE : DATE :	20 BOX	20 Box	Nil	HEROI (1053)	Nurin 24/1/22	24/01/22

STERILIZATION :

ETO

STERILIZATION DATE :

19-01-22

STERILIZATION BATCH NUMBER :

ETO 220143

FINAL SHIPMENT DATE

SHIPMENT QUANTITY PCS / CTNS :

120 / 20 box

COMPLETE/PARTIAL :

COMPLETE

RETAIN SAMPLE :

1 box

VMD SAMPLE :

Checked by (PR),

Signature: Ratnasegaran

Name: Ratnasegaran

Date: 28/1/22

Approved by (QA),

Signature: Ratnasegaran

Name: Ratnasegaran

Date: 4/2/2022

Released by (QC),

Signature: Martin

Name: MARTIN

Designation: QC Dept

Date: 27/01/2022

Stamp:

Remarks:

Mesh taken from Semi-Finish Mesh Shop Packet need to record below information for traceability;

1) Semi-finish Mesh Lot No. :

2) Mesh Supplier Lot No. :

3) Mesh Roll No.:



## LABEL PRINTING PROCESS

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

## LABEL APPROVAL

**VigiMesh** SIZE : 6 cm x 11 cm  
 REF : RM6110SP  
 LOT : A20802  
 2027-01

**VigiMesh™**  
 Polypropylene Mesh.  
 Knitted. Non-Absorbable.



**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.

CE 2292

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

**VigiMesh™**  
 Polypropylene Mesh.  
 Knitted. Non-Absorbable.



**Small Pore Standard Weight**

**SIZE: 6cm x 11cm**

QTY : 6 Pcs

REF RM6110SP

LOT A20802

2027-01

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# **LABEL PRINTING CHECKLIST - VIGIMESH**

DESCRIPTION	Vigimesh SP 6 x 11cm			
REF	RM6110SP		INNER POUCH	BOX LABEL
LOT NO	A20802	DATE PRINTED	15/1/2022	15/1/2022
EXP. DATE	2027-01	QTY PRINTED (PCS)	127	22
COUNTRY	VMS (MALAYSIA)	PRINTED BY	RSD1 857	RSD1 857
ORDER QTY	120 + 6	REMARK		

	SPECS	INNER POUCH		BOX LABEL	
		OK	NOT OK	OK	NOT OK
a. LABEL SELECTION	VIGIMESH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. REF NO	RM6110SP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. MESH SIZE	6 x 11cm	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. CE MARK	YES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e. LOT NO	A20802	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f. EXP DATE	2027-01	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g. SPECIAL REQUIREMENT	NIL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

CHECKED BY  
(QC / IPQC)  
Date :

Amir MARTIN  
15/01/2022

Doc. No : PR-LP003  
Rev: 0

VIGILENZ®	IN-PROCESS INSPECTION RECORD – SURGICAL HERNIA MESH	Doc. No.	QC-IP005
		Rev.	01

Reference / Lot No.	RM6110SP / A20802
Order Quantity	120

#### A) LASER CUTTING

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Mesh free from burr	54, 0.4	32	0	1	32	0	pass
2.	No contamination	54, 0.4	32	0	1	32	0	pass
3.	No burn marks	54, 0.4	32	0	1	32	0	pass
4.	Edges are well sealed	54, 0.4	32	0	1	32	0	pass
5.	No warping of mesh	54, 0.4	32	0	1	32	0	pass
6.	Dimension (Tolerance: +0.2cm/ -0cm)	54, 0.154	32	0	1	32	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)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

#### C) DRYING

Sampling	No presence of moisture	No discoloration	No damage or warping of mesh	Test Disposition (Pass / Fail)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

#### D) SLIT MESH ON SUPPORT CARD

Sampling	Correct Position of the Inserted Mesh	No Contamination on Mesh	No Contamination on Support Card	Test Disposition (Pass / Fail)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass



VIGILENZ®	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	✓	✓	pass
1/5	✓	✓	pass
2/5	✓	✓	pass
3/5	✓	✓	pass
4/5	✓	✓	pass
5/5	✓	✓	pass

#### F) POUCH SEALING

Sampling	Visual Inspection		Seal Integrity (first 4 pieces)				Seal width (9±1mm)	Test Disposition (Pass / Fail)
	Proper and consistent sealing seam	No melting defects	Seal strength (min 0.50 kgf)			Peel test (continuous sealing)		
			1	2	Average			
2/4	✓	✓	1.35	1.77	1.56 kgf	✓	✓	Pass
1/5	✓	✓	Instrument Used				✓	Pass
2/5	✓	✓					✓	pass
3/5	✓	✓					✓	pass
4/5	✓	✓					✓	Pass
5/5	✓	✓					✓	Pass

#### G) POUCH LABELLING

Sampling	Lot No. and Ref No. on Label corresponds to shop packet	Correct orientation of labeling on the pouch	Test Disposition (Pass / Fail)
5/5	✓	✓	Pass
1/5	✓	✓	Pass
2/5	✓	✓	Pass
3/5	✓	✓	Pass
4/5	✓	✓	Pass
5/5	✓	✓	Pass

\* Inspection criteria as per Control Plan QCCP-04.

REMARKS: N/A

Inspected By : Pavani  
Name : Pavani  
Date : 22/11/2022

Approved By : M. Martini  
Name : M. MARTINI  
Date : 22/01/2022

VIGILENZ®	FINAL CONTROL TEST REPORT – HERNIA MESH				Doc. No.	QC-FC002
					Rev	01

Reference Code	Zm6110SP		Lot. No.	A20802	
Item Description	vigimesh sp 6x11cm		Quantity Produced	120	Retain Sample
					1 box

No.	Inspection Criteria Ref. Doc.: QCCP-04	Sampling Details	Sample size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Labeling should correspond to shop packet (Outer Pouch & Box Label)	I, 0.15	80	0	1	80	0	pass
	Printing is clear and legible	I, 0.15	80	0	1	80	0	pass
	Correct labeling orientation	I, 0.15	80	0	1	80	0	pass
	Proper Sealing	I, 1.0	13	0	1	13	0	pass
	No foreign matters or particles inside package	I, 1.0	13	0	1	13	0	pass
	No warping / damage / discoloration	I, 1.0	13	0	1	13	0	pass
	Correct Pack Size	I, 0.15	80	0	1	80	0	pass

\* P= Pass / F=Fail

REMARKS: NA

Inspected By :	<u>P. Raj</u>	Verified By :	<u>M. J. J. J.</u>
Name :	<u>POSHANI</u>	Name :	<u>MARTINI</u>
Date :	<u>22/01/20</u>	Date :	<u>22/01/2022</u>




DATE	11/01/2022
REF	RM6110SP
LOT NO.	A20802

SHOP PACKET QTY (pcs)

CUSTOMER

I.O NO.

RS	120	**
VMS (MALAYSIA)		**
IO/VMS/060122/01		**

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)			RECEIVED BY
						REQUIRED	ISSUED	CONSUMPTION	
1	V0100002	Surgical Mesh Polypropylene ( PPKM 602, Standard )	VIGIMESH SP	6 X 11 cm	M020210601	pcs	2.65	2.65	

## (2) PRODUCT PACKAGING

(2) PRODUCT PACKAGING					RECEIVED BY
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	
1	P0100439	Support Card For Vigimesh - Size: 160mm x 165mm, Material: Artcard 230gm, 1 Color Printing	P01L200201	126	<u>1 Canjanga</u>
2	V0100024	181 mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE	P02C200201	126	<u>1 Canjanga</u>
3	V0100016	VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE	P108200201	20 + 1	<u>1 Canjanga</u>
4	P0100507	IF-SB-CNEN-LH Rev: 06, Size: 110mm x 110mm IFU Vigimesh	P070200201	20 + 1	<u>1 Canjanga</u>
5	V0100023	BL00003 - Printed Vigimesh Pouch Label, Size: 130mm x 60mm, Material: MP (New revision)	L1 20210701	147	<u>1 Canjanga</u>
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210502	20	<u>1 Canjanga</u>
7		#N/A			

### (3) OVER WRAPPING AND CARTON PACK

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100371	Corrugated Carton Box ( Part No. ZV07VIGILENZC ) - Size: 595 x 375 x 365mm, Printing Plate: P12697	P100210901	1	mclaly
2		#N/A			
3		#N/A			


(4) SPECIAL REQUIREMENT					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		NA	
2		#N/A			


ISSUED BY (MM) :

Signature : 

Name : LOVIN

Date : 11/01/2022

VERIFIED BY (PR) : 

Signature : 

Name : R. K. THAKUR

Date : 26/1/22

Peel test (apcs) passed on 19/01/2022





VIGILENZ®	PRODUCT RELEASE TEST REPORT – HERNIA MESH		Doc. No.	QC-PC004
			Rev.	04

Item Description	Vigimesh sp 6 x 11cm	Reference No.	RM6110SP	Date of Inspection	26/01/2022
Sterilization Process	E10	Lot No.	A20802	Sample Size	2 pcs
		Sterilization Batch No.	E10 220103	Sterilization Date	19/01/22

Visual Inspection				Physical Inspection	
Correct Labeling (Outer Pouch & Box Label)	Packing Integrity	Edges Are Well Sealed	Free from Warping and Damage of Mesh	No Discoloration of Mesh	Dimension (In-process) Tolerance: (+0.2cm / -0cm)
✓	✓	✓	✓	✓	1.44
					0.99
					1.32N/gf

✓ = Pass X = Fail

CONCLUSION: ☒ RELEASE ☐ ON-HOLD

REMARKS: NA

Inspected By: Pooja  
 Name: Poonam  
 Date: 26/01/2022

Approved By: [Signature]  
 Name: AARTINI  
 Date: 26/01/2022

