

SHOP PACKET - OPERATION (MESH)						
REF	RM1015LP	ODR. QTY	30	RS 1 BOX (3PCS)	ORDER NO.	A061
ITEM CODE	13000864	PACK SIZE	3/BXS	CUSTOMER	VMS (MALAYSIA)	
ITEM DESCRIPTION	VIGIMESH LP, 10 X 15cm	LOT NO:	A20803	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	10/VMS/060122/01	
	DATE : 10/01/2022		DATE : 10/01/2022			

PROCESS		START QTY	OUTPUT PCS	REJECT PCS	OPERATOR	IPQC APPROVAL	REMARKS
LASER CUTTING		33	33	Nil	Rusoi	Roshni 1:20 pm 11/1/22	NA
TIME START :	11:45 am						
DATE :	11-01-22						
TIME COMPLETE :	1:20 pm						
DATE :	11-01-22						
ULTRASONIC WASH		33	33	Nil	Zayana (790)	Roshni 2:50 pm 11/01/22	NA
TIME START :	2:45 pm						
DATE :	11-01-22						
TIME COMPLETE :	2:50 pm						
DATE :	11-01-22						
DRYING		33	33	Nil	Zayana (790)	Roshni 8:30 am 12/01/22	NA
TIME START :	2:00 pm						
DATE :	11-01-22						
TIME COMPLETE :	8:30 AM						
DATE :	12-01-22						
SLIT MESH ON SUPPORT CARD		33	33	Nil	viki (1094)	Roshni 3:00 pm 15/01/22	NA
TIME START :	3:00 pm						
DATE :	15-01-22						
TIME COMPLETE :	3:30						
DATE :	15-01-22						
SLOT INTO POUCH		33	33	Nil	viki (1094)	Roshni 4:00 pm 15/01/22	NA
TIME START :	3:30						
DATE :	15-01-22						
TIME COMPLETE :	4:00						
DATE :	15-01-22						
POUCH SEALING		33	33	Nil	Erg (932)	Rashni 04/01/22	Nil
TIME START :	1:34						
DATE :	19-01-22						
TIME COMPLETE :	1:39						
DATE :	19-01-22						
POUCH LABELLING		33	33	Nil	Tashq (1059)	Rashni 20/01/22	N/A
TIME START :	1:34						
DATE :	19-01-22						
TIME COMPLETE :	1:39						
DATE :	19-01-22						
BOX- PACKING & FINAL CONTROL		33	33	NIL	viki (1094) KALI (1078)	Roshni 5:25 pm 23/01/2022	NA
TIME START :	4:58 pm						
DATE :	22-01-22						
TIME COMPLETE :	5:25 pm						
DATE :	22-01-22						
SHRINK WRAP		10 Box	10 Box	Nil	FASLI (1054)	Jumma 25/01/22	8/8
TIME START :	10:15 am						
DATE :	24-01-22						
TIME COMPLETE :	10:25 am						
DATE :	24-01-22						
CARTON PACK		10 Box	10 Box	Nil	HERDI (1053)	Jumma 25/01/21	8/8 24/01/21
TIME START :	10:15 am						
DATE :	24-01-22						
TIME COMPLETE :	10:25 am						
DATE :	24-01-22						

STERILIZATION : ETO

STERILIZATION DATE : 19-01-22

STERILIZATION BATCH NUMBER : ET0220143

FINAL SHIPMENT DATE :

SHIPMENT QUANTITY PCS / CTNS : 70 pcs / 10 box

COMPLETE/PARTIAL : COMPLETE

RETAIN SAMPLE : 1 box

VMD SAMPLE : n/a

STERILE

Checked by (PR),

Signature: *[Signature]*

Name: Ratnasegaran

Date: 26/1/22

Approved by (QA),

Signature: *[Signature]*

Name: Ratnasegaran

Date: 4/2/2022

Released by (QC),

Signature: *[Signature]*

Name: MARTINI

Designation: QC REPT

Date: 27/01/2022

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 :		<hr/>		N/A	<hr/>										
DATE :	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>														
TIME COMPLETE :															
DATE :	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>														
PRINTING BOX LABEL															
TIME START :		<hr/>		N/A	<hr/>										
DATE :	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>														
TIME COMPLETE :															
DATE :	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>														

LABEL APPROVAL

VigiMesh	SIZE :	10 cm x 15 cm
REF	:	RM1015LP
LOT	:	A20803
	:	2027-01

VigiMesh™

Polypropylene Mesh.
Knitted. Non-Absorbable.



Small Pore Light Weight

SIZE: 10cm x 15cm

REF RM1015LP

LOT A20803

2027-01

MDA NO. GC1209349316

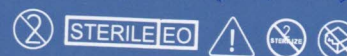


Manufactured by:
VIGILENZ MEDICAL DEVICES Sdn. Bhd.
308 b, Penang Science Park,
14100 Penang, Malaysia.

CE 2292 EC REP OBELIS S.A.
BD. GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM

VigiMesh™

Polypropylene Mesh.
Knitted. Non-Absorbable.



Small Pore Light Weight

SIZE: 10cm x 15cm

QTY : 3 Pcs

REF RM1015LP

LOT A20803

2027-01

MDA NO. GC1209349316



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LABEL PRINTING CHECKLIST - VIGIMESH

DESCRIPTION	VIGIMESH LP, 10 X 15cm			
REF	RM1015LP		INNER POUCH	BOX LABEL
LOT NO	A20803	DATE PRINTED	15/1/2022	15/1/2022
EXP. DATE	2027-01	QTY PRINTED (PCS)	34	12
COUNTRY	VMS (MALAYSIA)	PRINTED BY	2201/2022	2201/2022
ORDER QTY	30 + 3	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	RM1015LP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. MESH SIZE	10 x 15cm	<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	A20803	<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 :

15/01/2022
MARTINI

Doc. No : PR-LP003
Rev: 0

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

Reference / Lot No.	RM1015LP / A20803
Order Quantity	20

A) LASER CUTTING

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Mesh free from burr	SH. 04	32	0	1	32	0	pass
2.	No contamination	SH. 04	32	0	1	32	0	pass
3.	No burn marks	SH. 04	32	0	1	32	0	pass
4.	Edges are well sealed	SH. 04	32	0	1	32	0	pass
5.	No warping of mesh	SH. 04	32	0	1	32	0	pass
6.	Dimension (Tolerance: +0.2cm/ -0cm)	SH. 04	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			
4/4	✓	✓	0.70	0.96	0.83 kgf	—	✓	Pass
1/5	✓	✓	Instrument Used				✓	Pass
2/5	✓	✓					✓	Pass
3/5	✓	✓					✓	Pass
4/5	✓	✓					✓	Pass
5/5	✓	✓					✓	Pass
			QC-92, QC-02				✓	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 : Poovny
Name : Poovny
Date : 27/01/2022

Approved By : MARTINI
Name : MARTINI
Date : 27/01/2022

VIGILENZ®

FINAL CONTROL TEST REPORT – HERNIA MESH

Doc. No.	QC-FC002
Rev	01

Reference Code	RM 1015LP	Lot. No.	A 20803	
Item Description	Vigimash LP, 10 x 15cm	Quantity Produced	33	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	33	0	1	33	0	pass
	Printing is clear and legible	I, 0.15	33	0	1	33	0	pass
	Correct labeling orientation	I, 0.15	33	0	1	33	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	33	0	1	33	0	pass

* P= Pass / F=Fail

REMARKS: NA

Inspected By :	<u>Raj</u>
Name :	<u>ROHINI</u>
Date :	<u>22/01/22</u>

Verified By :	<u>M. S. Srinivas</u>
Name :	<u>MARTINI</u>
Date :	<u>22/01/2022</u>

VIGILENZ®

Doc. No. 06
Rev.

RAW MATERIAL LOADING FORM (RLF)

DATE : 11/01/2022

REF : RM6110LP

LOT NO. : A20803

SHOP PACKET QTY (pcs) : 30

CUSTOMER : VMS (MALAYSIA)

LO NO. : IOVMS060122/01

RS 3

RECEIVED BY : *i. Tanjung*

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY	
						REQUIRED	ISSUED		
1	V0100001	Surgical Mesh Polypropylene (PPKM 404 ,Light Weight)	VIGIMESH LP	10 X 15 cm	M020210601	pcs	1.73	1.73	<i>i. Tanjung</i>

(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 363mm, Printing Plate P12697	P100210901	1	<i>maluku</i>
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)		~11	
2		#N/A			

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100439	Support Card For Vigimesh - Size: 160mm x 165mm, Material: Artcard 230gm, 1 Color Printing	P011200201	33	<i>i. Tanjung</i>
2	V0100024	181mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE	P02C200201	33	<i>i. Tanjung</i>
3	V0100016	VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE	P108200201	10 + 1	<i>i. Tanjung</i>
4	P0100507	IF-SB-CNEN-LH Rev: 06, Size: 110mm x 110mm IFU Vigimesh	P070200201	10 + 1	<i>i. Tanjung</i>
5	V0100023	BL00003 - Printed Vigimesh Pouch Label, Size: 130mm x 60mm, Material: MP (New revision)	L120210701	44	<i>i. Tanjung</i>
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gd) SIZE: 85mm X 65mm	L190210502	10 + 1	<i>i. Tanjung</i>
7		#N/A			

ISSUED BY (MM) :

Signature : *[Signature]*
Name : LOVIN
Date : 11/01/2022

VERIFIED BY (PR) :

Signature : *[Signature]*
Name : *[Signature]*
Date : 26/1/22

Peel test (9pc3) passed on 19/01/2022



PRODUCT RELEASE TEST REPORT – HERNIA MESH

QC-PC004

04

Item Description	Reference No.	Date of Inspection	26/01/2022
Sterilization Process	Lot No.	Sample Size	2PCS
	Sterilization Batch No.	Sterilization Date	19/01/2022

Visual Inspection					Dimension (In-process) Tolerance: (+0.2cm / -0cm)	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		1	2	Average
✓	✓	✓	✓	✓	10.2cm x 15.2cm	0.69	1.20	0.95 kgf

✓ = Pass X = Fail

RELEASE

ON-HOLD

REMARKS:

Inspected By:

Name _____

Date _____

Approved By :

Name

Date _____

