

## SHOP PACKET - OPERATION (MESH)

REF	RM6110SP	ODR. QTY	144	RS: 1	ORDER NO.	A106
ITEM CODE	13000857	PACK SIZE	6/BXS	CUSTOMER	VMD (MALAYSIA)	
ITEM DESCRIPTION	Vigimesh SP 6 x 11cm	LOT NO:	A11905	MFG DATE	19-Jan-21	
PREPARED BY	NAME : SITI NORSHAFIQAH DATE : 19/01/2021	ISSUED DATE	19-Jan-21	EXP DATE	2026-01	
		VERIFIED BY	NAME : MUNIRAJA DATE : 19/01/2021	INT. ORDER	IO/VMD/180121/01	

PROCESS	START QTY	OUTPUT PCS	REJECT PCS	OPERATOR	IPQC APPROVAL	REMARKS
LASER CUTTING						
TIME START : DATE : TIME COMPLETE : DATE :	09:00 am 09-02-21 10:00 am 09-02-21	145	145	NIL	RUSD1 (857) Zahidah (821) Kerina (948) 09/02/2021	Ellypt 9.0mm Cynthia 10.0mm 09/02/2021
ULTRASONIC WASH						
TIME START : DATE : TIME COMPLETE : DATE :	3:10 PM 09-02-21 3:15 PM 09-02-21	145	145	NIL	Rashmi 3:15 pm 09/02/2021	NA
DRYING						
TIME START : DATE : TIME COMPLETE : DATE :	3:45 PM 09-02-21 8:30 PM 10-02-21	145	145	NIL	Rashmi 8:30 pm 10/02/2021	NA
SPLIT MESH ON SUPPORT CARD						
TIME START : DATE : TIME COMPLETE : DATE :	9:40 am 11-02-21 11:50 am 11-02-21	145	145	NIL	Rashmi 11:50 AM 11/02/2021	NA
SLOT INTO POUCH						
TIME START : DATE : TIME COMPLETE : DATE :	9:15 am 16-02-21 9:45 am 16-02-21	145	145	NIL	Kyti (890)	Rashmi 9:45 AM 16/02/2021
POUCH SEALING						
TIME START : DATE : TIME COMPLETE : DATE :	10:00 am 16-02-21 11:00 am 16-02-21	145	145	NIL	Kyti (890)	Rashmi 11:00 AM 16/02/2021
POUCH LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	2:25 PM 16-02-21 3:20 PM 16-02-21	145	145	NIL	Kyti (890)	Rashmi 3:20 PM 16/02/2021
BOX-PACKING & FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	9:30 am 22-02-21 10:25 am 22-02-21	145	145	NIL	Kyti (890) Nasuhah (981)	Rashmi 6:10pm 22/02/2021
SHRINK WRAP						
TIME START : DATE : TIME COMPLETE : DATE :	11:16 AM 24-02-21 11:46 AM 24-02-21	24 box	24 box	NIL	Kyti (887)	FINISH 24/02/21
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	11:17 AM 24-02-21 11:48 AM 24-02-21	24 box	24 box	NIL	Zarzhi C376	FINISH 24/02/21

STERILIZATION : ETO  
 STERILIZATION DATE : 18-02-21  
 STERILIZATION BATCH NUMBER : ETO210011  
 FINAL SHIPMENT DATE :  
 SHIPMENT QUANTITY PCS / CTNS : 144 pcs  
 COMPLETE/PARTIAL : COMPLETE PARTIAL  
 RETAIN SAMPLE : 1 PCS  
 VMD SAMPLE : -

Checked by (PR), Signature: <i>Muniraja</i> Name: M. Muniraja Date: 24/02/2021	Approved by (QA), Signature: <i>D</i> Name: M. Lalguman Date: 24/02/2021	Released by (QC), Signature: <i>D</i> Name: A. Devi Designation: IPQC Supervisor Date: 24/02/2021
Remarks: Mesh taken from Semi-Finish Mesh Shop Packet need to record below information for traceability; <ol style="list-style-type: none"> <li>1) Semi-finish Mesh Lot No.: NA 20 box size for mesh ICT-TMT</li> <li>2) Mesh Supplier Lot No.: NA 4 box size for rms</li> <li>3) Mesh Roll No.: NA</li> </ol>		
Stamp:  Date: 24/02/2021		

STERILE *Hal.*  
24/02/2021

## LABEL PRINTING PROCESS

PROCESS	START QTY PCS	OUTPUT PCS	OPERATOR	REJECT PCS	IPQC APPROVAL	REMARKS
PRINTING POUCH LABEL						
TIME START : DATE :	10:45 am 11 - 02 - 21					
TIME COMPLETE : DATE :	11:10 am 11 - 02 - 21					
PRINTING BOX LABEL						
TIME START : DATE :	11:00 am 11 - 02 - 21					
TIME COMPLETE : DATE :	11:10 am 11 - 02 - 21					

## LABEL APPROVAL

CHECKED BY  
(QC / IPQC)  
Date :

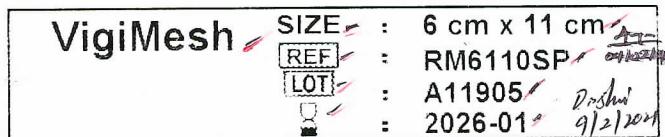
De Ann  
18/02/2024

Doc. No : PR-LP003  
Rev: 0

LABEL PRINTING PROCESS

PROCESS	START QTY PCS	OUTPUT PCS	OPERATOR	REJECT PCS	IPQC APPROVAL	REMARKS
PRINTING POUCH LABEL						
TIME START : 10:45 am DATE : 11-02-21 TIME COMPLETE : 11:10 am DATE : 11-02-21	146	146	RUSI JS	NIL	Roshni 11:10 AM 11/02/2021	NA
PRINTING BOX LABEL						
TIME START : 11:00 am DATE : 18-02-21 TIME COMPLETE : 11:10 am DATE : 18-02-21	25	25	RUSI JS	NIL	Roshni 11:10 AM 18/02/2021	NA

LABEL APPROVAL



VigiMesh™

Polypropylene Mesh.  
Knitted. Non-Absorbable.



Small Pore Standard Weight

SIZE: 6cm x 11cm

RUSI JS  
11/21/21

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

MDA NO . GC1209349316

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Polypropylene Mesh.  
Knitted. Non-Absorbable.



Small Pore Standard Weight

SIZE: 6cm x 11cm

RUSI JS  
18/21/21

Manufactured by:  
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BD. GENERAL WAHIS 53  
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MDA NO . GC1209349316

VIGILENZ®

IN-PROCESS INSPECTION RECORD –  
SURGICAL HERNIA MESH

Doc. No.	QC-IP005
Rev.	01

Reference / Lot No.	RMG110SP / A 11905
Order Quantity	145

## A) LASER CUTTING

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (Pass / Fail)
				Accept	Reject	Accept	Reject	
1.	Mesh free from burr	S4, 0.4	8	0	1	8	0	PASS
2.	No contamination	S4, 0.4	8	0	1	8	0	PASS
3.	No burn marks	S4, 0.4	8	0	1	8	0	PASS
4.	Edges are well sealed	S4, 0.4	8	0	1	8	0	PASS
5.	No warping of mesh	S4, 0.4	8	0	1	8	0	PASS
6.	Dimension (Tolerance: +0.2cm/ -0cm)	S4, 0.4	8	0	1	8	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-IP003

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)
1/5	✓	✓	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)						
			1	2	Average				
1/4	✓	✓	0.73	0.63	0.68 kgf	✓	PASS		
1/5	✓	✓	Instrument Used				PASS		
2/5	✓	✓					PASS		
3/5	✓	✓	ØC-92, ØC-02				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 : Roshni  
Name : Roshni  
Date : 16/02/2021Approved By : J  
Name : J. Dewi  
Date : 16/02/2021

VIGILENZ®

## FINAL CONTROL TEST REPORT - HERNIA MESH

Doc. No.

QC-FC002

Rev

01

Reference Code	RMG110SP	Lot. No.	A11905		
Item Description	vigi mesh sp 6x11 cm	Quantity Produced	144+1	Retain Sample	1 pc

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	8	0	1	8	0	PASS
	Printing is clear and legible	I, 0.15	8	0	1	8	0	PASS
	Correct labeling orientation	I, 0.15	8	0	1	8	0	PASS
	Proper Sealing	I, 1.0	8	0	1	8	0	PASS
	No foreign matters or particles inside package	I, 1.0	8	0	1	8	0	PASS
	No warping / damage / discoloration	I, 1.0	8	0	1	8	0	PASS
	Correct Pack Size	I, 0.15	8	0	1	8	0	PASS

\* P= Pass / F=Fail

REMARKS: M/A

Inspected By : Roshni  
 Name : ROSHNI  
 Date : 22/02/2021

Verified By : Devi  
 Name : A. Devi  
 Date : 22/02/2021

VIGILENZ®

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

DATE : 20/01/2021  
 REF : RM6110SP  
 LOT NO. : A11905

SHOP PACKET QTY (pcs) : 144  
 CUSTOMER : VMD (MALAYSIA)  
 I.O NO. : IO/VMD/180121/01

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	M020200301	pcs	3.05	3.05	3-10 RSdi 887

## (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	P01L91101	145	Firjauq (790)
2	V0100008	181mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE -	P02C90401	145	Firjauq (790)
3	V0100016	VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE	P10890601	24	Firjauq (790)
4	P0100507	IFU Vigimesh (VMD-IFU-018) - Rev: 05, Size: 110mm x 110mm	P070200201	24	Firjauq (790)
5	V0100023	BL00003 - Printed Vigimesh Pouch Label, Size:130mm x 60mm, Material: MP (New revision)	L120200101	170	Firjauq (790)
6		#N/A			
7		#N/A			

ISSUED BY (MM) :

Signature :   
 Name : FIRDAUS  
 Date : 20/01/2021

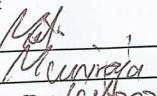
## (3) OVER WRAPPING AND CARTON PACK

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	P100200901	1	Anjy
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)		N/A	
2		#N/A			

VERIFIED BY (PR) :

Signature :   
 Name : Munirah  
 Date : 20/01/2021

peel Test opcs passed on 16/02/2021



VIGILENZ®

**PRODUCT TRANSFER SLIP –  
ETO STERILIZATION & HYDROCYN ITEMS**

Doc No.	PR-TS003
Rev	00

Date	23/02/2021			Lot No	A11905	
Product Detail	Vijimesh			Customer	VMJ	
Reference No.	RM6110SP			Sterilization	ETO (Yes / No)	
Order Qty	144	Retain Sample Qty	1			
Final Packaging Process						
Process	Input Qty	Output Qty	Rejects	Operator	QC Approval	Remarks
OVERWRAPPING	24 box	24 box	N/A	Khy (0887)		N/A
	TIME START : 11:16AM	TIME COMPLETE : 11:46AM				
ARTON PACK	24 box	24 box	N/A	Zarchi (376)		Sem. Sun 24/02/2021
	TIME START : 11:17AM	TIME COMPLETE : 11:48AM				
	DATE : 24/02/2021	DATE : 24/02/2021				
OQC Inspection	Inspected by:  LUNDA			Date: 24/02/21 Status:	Release <input type="checkbox"/>	Onhold <input type="checkbox"/>
Remarks	N/A					

**PRODUCT RELEASE TEST**

Item Description	Vijimesh Spec 11cm	Reference No.	
		Lot No.	
Sterilization Process	ETO	Sterilization Batch	

**Visual Inspection**

Correct Labeling (Outer Pouch & Box Label)	Packing Integrity	Edges Are Well Sealed	Free from Warping and Damage of Mesh	Disc of	
				✓	✗
				✓	✗

✓ = Pass X = Fail

CONCLUSION:  RELEASE  
 ON-HOLD

REMARKS : N/A

Inspected By:   
Name :   
Date : 24/02/2021

VIGILENZ®

## PRODUCT RELEASE TEST REPORT - HERNIA MESH

Doc. No.	QC-PC004
Rev.	04

Item Description	vigi mesh sp6 x 11cm	Reference No.	RM6110SP	Date of Inspection	24/02/2021
		Lot No.	A11905	Sample Size	1 pc
Sterilization Process	ETO	Sterilization Batch No.	ETO 210011	Sterilization Date	18/02/2021

Visual Inspection					Dimension (In-process) Tolerance: (+0.2cm / -0cm)	Physical Inspection			
						Pouch Seal Strength (after ETO Sterilization) Min 0.50 kgf			
Correct Labeling (Outer Pouch & Box Label)	Packing Integrity	Edges Are Well Sealed	Free from Warping and Damage of Mesh	No Discoloration of Mesh		Instrument used: ØC-02 - ØC-92	1	2	Average
✓	✓	✓	✓	✓	6.1cm x 11.2cm	0.82 kgf	0.84 kgf	0.83 kgf	

✓ = Pass X = Fail

CONCLUSION:  RELEASE ON-HOLD

REMARKS: N/A

Inspected By: Roshni

Name : Roshni

Date : 24/02/2021

Approved By: Jyoti

Name : A. Devi

Date : 24/02/2021

