

SHOP PACKET - OPERATION (SEMI-FINISH MESH)

REF	RM6110SP	ODR. QTY	600	RS: 1	ISSUED DATE	2-Jan-20
ITEM CODE	13000857	PACK SIZE	6/BXS	LOT NO.	A002SF09	
ITEM DESCRIPTION	Vigimesh SP 6 x 11cm	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	2-Jan-20	
		ODR. NO.	A010	EXP DATE	2025-01	
PREPARED BY	NAME : NUR HASMAWATI	VERIFIED BY	NAME : MUNIRAJA			
	DATE : 02/01/2020		DATE : 02/01/2020			

PROCESS		START QTY PCS	OUTPUT PCS	REJECT PCS	OPERATOR	IPQC APPROVAL	REMARKS
LASER CUTTING		600	600	nil	Jahidien (821)	Cynthia 11.40am 04/02/2020	NA
TIME START :	09.00 am						
DATE :	04-02-20						
TIME COMPLETE :	11.40 am						
DATE :	04-02-20						
ULTRASONIC WASH		600	600	NIL	Rusdi (857)	Cynthia 4.00pm 04/02/2020	NA
TIME START :	11.45 am						
DATE :	04-02-20						
TIME COMPLETE :	4.00 pm						
DATE :	04-02-20						
DRYING		600	600	NIL	Rusdi (857)	Cynthia 10.00am 10/02/2020	NA
TIME START :	1.00 pm						
DATE :	04-02-20						
TIME COMPLETE :	10.00 am						
DATE :	10-02-20						
STORAGE		600	600	NIL	Rusdi (857)	Cynthia 5.00pm 10/02/2020	NA
TIME START :	10.00 am						
DATE :	10-02-20						
TIME COMPLETE :	5.00 pm						
DATE :	10-02-20						

Checked by (PR), Signature : <u>Muniraja</u> Name : <u>Muniraja</u> Date : <u>10/02/2020</u>	Approved by (QA), Signature : _____ Name : _____ Date : _____
REMARKS : 	

[illegible]

VIGILENZ®	IN-PROCESS INSPECTION RECORD – SURGICAL HERNIA MESH	Doc. No.	QC-IP005
		Rev.	00

Reference / Lot No.	R/m6110SP / A0028 F09
Order Quantity	601

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	20	0	1	20	0	PASS
2.	No contamination	S4, 0.4	20	0	1	20	0	PASS
3.	No burn marks	S4, 0.4	20	0	1	20	0	PASS
4.	Edges are well sealed	S4, 0.4	20	0	1	20	0	PASS
5.	No warping of mesh	S4, 0.4	20	0	1	20	0	PASS
6.	Dimension (Cut size \pm 0.2cm)	S4, 0.4	20	0	1	20	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)
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)
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)
		NA		

E) SLOT INTO POUCH

Sampling	Correct Position of the Support Card	No tear, deformed, damage or contamination on pouch	Test Disposition (Pass / Fail)
		NA	

F) POUCH SEALING

Sampling	Proper and consistent sealing seam		No melting defects		NA							
	Seal strength (min 0.50 kgf)		1	2						Average	Seal width (9 ±1mm)	Peel test (continuous sealing)
	Visual Inspection			Seal Integrity (first 2 pieces)								
Test Disposition (Pass / Fail)												

G) POUCH LABELLING

Sampling	Lot No. and Ref No. on label corresponds to shop packet	Correct orientation of labelling on the pouch	Test Disposition (Pass / Fail)
		NA	

* Inspection criteria as per Control Plan QCCP-04.

REMARKS:

Inspected By

Name_____

Date _____

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Signature

5. CANTHA

10/02/2021

Approved By :

Name _____

Date _____

M. Luggman

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VIGILENZ®

RAY MATERIAL LOADING FORM (RMF)

Doc. No. PR-101
Rev. 06

DATE : 11-01-2020

REF : RM6110SP

LOT NO. : A002SF09

SHOP PACKET QTY (pcs) :

600

RS

CUSTOMER :

VMD (MALAYSIA)

LO NO. :

IO/VMD/121219/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		CONSUMPTION	RECEIVED BY
						REQUIRED	ISSUED		
1	V0100002	Surgical Mesh Polypropylene (PPKM 602, Standard)	VIGIMESH SP 6 X 11 cm	M02090101/1	mt	12.62	12.62	12.62	Rupdy (8575)

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY

ISSUED BY (MM) :

Signature :



Name :

NORSALAHUDDIN

Date :

11-01-2020

VERIFIED BY (PR) :

Signature :



Name :

Murnira

Date :

11/01/2020