

SHOP PACKET - OPERATION (MESH)						
REF	RM6110SP	ODR. QTY	288	RS 1 BOX (6PCS)	ORDER NO.	A062
ITEM CODE	13000857	PACK SIZE	6/BXS	CUSTOMER	PT HOSPI MEDIK (INDONESIA)	
ITEM DESCRIPTION	Vigimesh SP 6 x 11cm	LOT NO:	A20804	MFG DATE	11-Jan-22	
		ISSUED DATE	11-Jan-22	EXP DATE	2027-01	
PREPARED BY	NAME : NUR SHAHIRA	VERIFIED BY	NAME : RATNASEGARAN	INT. ORDER	IO/PTS/004504/05	
	DATE : 11/01/2022		DATE : 11/01/2022			

PROCESS		START QTY	OUTPUT PCS	REJECT PCS	OPERATOR	IPQC APPROVAL	REMARKS
LASER CUTTING		294	294	Nil	Sulindan 821	Poshni 4:00pm	NA
TIME START :	3:10 pm						
DATE :	11-01-22						
TIME COMPLETE :	4:00 pm						
DATE :	11-01-22						
ULTRASONIC WASH		294	294	Nil	Canjano (798)	Poshni 10:30 pm 13/01/2022	NA
TIME START :	10:20 pm						
DATE :	13-01-22						
TIME COMPLETE :	10:30 pm						
DATE :	13-01-22						
DRYING		294	294	Nil	Canjano (798)	Poshni 8:30am 14/01/22	NA
TIME START :	10:50 am						
DATE :	13-01-22						
TIME COMPLETE :	8:30 am						
DATE :	14-01-22						
SLIT MESH ON SUPPORT CARD		294	294	Nil	vikneswary (1094)	Poshni 10:30am 15/01/22	NA
TIME START :	09:05 am						
DATE :	15-01-22						
TIME COMPLETE :	10:30 am						
DATE :	15-01-22						
SLOT INTO POUCH		294	294	Nil	vikneswary (1094)	Poshni 12:00pm 15/01/22	NA
TIME START :	10:30						
DATE :	15-01-22						
TIME COMPLETE :	12:00						
DATE :	15-01-22						
POUCH SEALING		294	294	Nil	Era (932)	Poshni 5:10pm 19/01/22	Avg: 0.92 kgf
TIME START :	4:21						
DATE :	19-01-22						
TIME COMPLETE :	5:10 PM						
DATE :	19-01-22						
POUCH LABELLING		294	294	Nil	Tasha (1089)	Poshni 5:10pm 19/01/22	NA
TIME START :	4:21						
DATE :	19-01-22						
TIME COMPLETE :	5:10 PM						
DATE :	19-01-22						
BOX- PACKING & FINAL CONTROL		294	294	Nil	Netra (1103) Era (932)	Poshni 12:00pm 20/01/22	NA
TIME START :	10:10 am						
DATE :	22-01-22						
TIME COMPLETE :	12:00 PM						
DATE :	22-01-22						
SHRINK WRAP		48 Box	48 box	Nil	FASLI (1054) RABIN (1088)	Nurin 25/1/22	N/A
TIME START :	10:45 am						
DATE :	24-01-22						
TIME COMPLETE :	11:05 am						
DATE :	24-01-22						
CARTON PACK		48 Box	48 box	Nil	HEROI (1053)	Nurin 25/1/22	25/01/2022
TIME START :	10:45 am						
DATE :	24-01-22						
TIME COMPLETE :	11:05 am						
DATE :	24-01-22						

STERILIZATION : ETO

STERILIZATION DATE : 19-01-22

STERILIZATION BATCH NUMBER : ETO220143

FINAL SHIPMENT DATE :

SHIPMENT QUANTITY PCS / CTNS : 288 pcs / 48 box

COMPLETE/PARTIAL : COMPLETE

RETAIN SAMPLE : 1 box (6 pcs)

VMD SAMPLE :

Checked by (PR),

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

Approved by (QA),

Signature: *[Signature]*
 Name: RABIN (1088)
 Date: 4/2/2022

Released by (QC),

Signature: *[Signature]*
 Name: MARTINI
 Designation: QC Dept
 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. :



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

LABEL APPROVAL

VigiMesh™

SIZE : 6 cm x 11 cm

REF : RM6110SP

LOT : A20804

2027-01

11-01/22
11-01/22
11-01/22

Diimport dan Diedarkan Oleh :
PT Hospi Medik Indonesia
Gedung Indra Sentral Blok E-F Lantai 1-2
Jl. Lejen Suprpto No. 60
Cempaka Putih, Jakarta Pusat
KEMENKES RI AKL 21602714030

VigiMesh™

Knitted, Non-Absorbable.
Polypropylene Mesh.

Small Pore Standard Weight

SIZE: 6cm x 11cm

REF RM6110SP
LOT A20804
2027-01

MDA NO. GC1209349316

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

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

CE 2292

STERILE EO

15/1/2022

VigiMesh™

Knitted, Non-Absorbable.
Polypropylene Mesh.

Small Pore Standard Weight

SIZE: 6cm x 11cm

QTY : 6 Pcs

REF RM6110SP
LOT A20804
2027-01

MDA NO. GC1209349316

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CE 2292

STERILE EO

15/1/2022

LABEL PRINTING CHECKLIST - VIGIMESH

DESCRIPTION	Vigimesh SP 6 x 11cm
REF NO	RM6110SP
LOT NO	A20804
EXP DATE	2027-01
COUNTRY	PT HOSPI MEDIK (INDONESIA)
ORDER QTY	288 + 6
DATE PRINTED	15/11/2022
QTY PRINTED (PCS)	288
PRINTED BY	Person Sign
REMARK	Person Sign
INNER POUCH	OK
BOX LABEL	OK

INNER POUCH	BOX LABEL
OK	OK
NOT OK	NOT OK
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

SPECS
VIGIMESH
RM6110SP
6 x 11cm
YES
A20804
2027-01
NIL

LABEL SELECTION
REF NO
MESH SIZE
CE MARK
LOT NO
EXP DATE
SPECIAL REQUIREMENT

CHECKED BY
(QC / IPQC)
Date :

Signature
15/01/2022

VIGILENZ® IN-PROCESS INSPECTION RECORD - SURGICAL HERNIA MESH		Doc. No. QC-IP005 Rev. 01
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Reference / Lot No. <i>Pm61ncsp / A2884</i>	Order Quantity <i>288</i>
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A) LASER CUTTING

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status
				Accept	Reject	Accept	Reject	
1.	Mesh free from burr	54, 0.4	32	0	21	32	0	pass
2.	No contamination	54, 0.4	32	0	21	32	0	pass
3.	No burn marks	54, 0.4	32	0	21	32	0	pass
4.	Edges are well sealed	54, 0.4	32	0	21	32	0	pass
5.	No warping of mesh	54, 0.4	32	0	21	32	0	pass
6.	Dimension (Tolerance: +0.2cm/-0cm)	54, 0.4	32	0	21	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®	FINAL CONTROL TEST REPORT – HERNIA MESH		Doc. No.	QC-FC002
			Rev	01

Reference Code	RMC110SP		Lot. No.	A20804
Item Description	vfigimesh 3p6x11cm		Quantity Produced	294
			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>Pouy</u>	Verified By	:	<u>[Signature]</u>
Name	:	<u>POSHNI</u>	Name	:	<u>AAKASH</u>
Date	:	<u>24/01/2022</u>	Date	:	<u>24/01/2022</u>

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

DATE : 11/01/2022

REF : RM6110SP

LOT NO. : A20804

Doc No. : 288

Rev. : RS

SHOP PACKET QTY (pcs) : 288


CUSTOMER : PT HOSPI MEDIK (INDONESIA)

LO NO. : IO/PTS/004504/05

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	V0100002	Surgical Mesh Polypropylene (PPKM 602, Standard)	VIGIMESH SP	6X 11 cm	M020210601	pcs	6.17	6.17	1. Kanjaya

(2) PRODUCT PACKAGING						(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	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	P01L200201	294	Kanjaya	1	P0100371	Corrugated Carton Box (Part No: ZV07VIGILENZC) - Size: 595 x 375 x 365mm, Printing Plate P12697	P100210901	1	meball
2	V0100024	181mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE	P02C200201	294	Kanjaya	2		#N/A			
3	V0100016	VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE	P108200201	48	Kanjaya	3		#N/A			
4	P0100507	IF-SB-CNEN-LH Rev: 06, Size: 110mm x 110mm IFU Vigimesh	P070200201	48	Kanjaya	(4) SPECIAL REQUIREMENT					
5	V0100023	BL00003 - Printed Vigimesh Pouch Label, Size: 130mm x 60mm, Material: MP (New revision)	L120210701	343	Kanjaya	NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
6	P0100208	BLANK LABEL (Sharps Pad/ Gauze/ Gel) SIZE: 85mm X 65mm	L190210502	48	Kanjaya	1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		17	
7		#N/A				2		#N/A			


ISSUED BY (MM) :

Signature : 

Name : LOVIN

Date : 11/01/2022

VERIFIED BY (PR) :

Signature : 

Name : KATIKREGRAN

Date : 26/1/2022

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

Item Description	Reference No.	Date of Inspection
Vigimesh sp 6 x 11cm	2m6110 SP	26/01/2022
	Lot No.	Sample Size
	A20804	2 PCS
Sterilization Process	Sterilization Batch No.	Sterilization Date
E10	E10 220143	19/01/2022

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)	Pouch Seal Strength (after ETO Sterilization) Min 0.50 kgf Instrument used: 01-02, 0092
✓	✓	✓	✓	✓	6.2cm x 11.2cm	0.63 0.83 0.73 kgf

✓ = Pass X = Fail

CONCLUSION: ☒ RELEASE

☐ ON-HOLD

REMARKS : N/A



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

Inspected By : [Signature]
Name : ROSHNI
Date : 26/01/2022