

| SHOP PACKET - OPERATION (MESH) | | | | | | |
|--------------------------------|-----------------------|-------------|---------------------|-----------------|------------------|------|
| REF | RM6110LP | ODR. QTY | 30 | RS 1 BOX (6PCS) | ORDER NO. | A059 |
| ITEM CODE | 13000862 | PACK SIZE | 6/BXS | CUSTOMER | VMS (MALAYSIA) | |
| ITEM DESCRIPTION | VIGIMESH LP, 6 X 11cm | LOT NO: | A20801 | 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 |
|----------------------------|----------|-----------|------------|------------|--|---------------------------------|---------------------------------|
| LASER CUTTING | | 36 | 36 | ML | Rashni 87 | Rashni 10:40am 11/01/2022 | NA |
| TIME START : | 10:20 am | | | | | | |
| DATE : | 11-01-22 | | | | | | |
| TIME COMPLETE : | 10:40 am | | | | | | |
| DATE : | 11-01-22 | | | | | | |
| ULTRASONIC WASH | | 36 | 36 | Nil | Caujano (790) | Rashni 2:50 pm 11/01/2022 | NA |
| TIME START : | 2:45 PM | | | | | | |
| DATE : | 11-01-22 | | | | | | |
| TIME COMPLETE : | 2:58 PM | | | | | | |
| DATE : | 11-01-22 | | | | | | |
| DRYING | | 36 | 36 | Nil | Caujano (790) | Rashni 8:30am 12/01/22 | NA |
| TIME START : | 3:00 PM | | | | | | |
| DATE : | 11-01-22 | | | | | | |
| TIME COMPLETE : | 8:30 AM | | | | | | |
| DATE : | 12-01-22 | | | | | | |
| SLIT MESH ON SUPPORT CARD | | 36 | 36 | Nil | Viki (1094) | Rashni 9:30am 15/01/22 | NA |
| TIME START : | 4:00 | | | | | | |
| DATE : | 15-01-22 | | | | | | |
| TIME COMPLETE : | 4:30 | | | | | | |
| DATE : | 15-01-22 | | | | | | |
| SLOT INTO POUCH | | 36 | 36 | Nil | Viki (1094) | Rashni 5:00pm 15/01/2022 | NA |
| TIME START : | 4:30 | | | | | | |
| DATE : | 15-01-22 | | | | | | |
| TIME COMPLETE : | 5:00 | | | | | | |
| DATE : | 15-01-22 | | | | | | |
| POUCH SEALING | | 36 | 36 | Nil | ERA (132) | Rashni 04/01/2022 | Reel Seal Strength Avg: 0.86 |
| TIME START : | 1:00 | | | | | | |
| DATE : | 19-01-22 | | | | | | |
| TIME COMPLETE : | 1:20 | | | | | | |
| DATE : | 19-01-22 | | | | | | |
| POUCH LABELLING | | 36 | 36 | Nil | Tasha (1089) | Rashni 24/01/2022 | N/A |
| TIME START : | 1:00 | | | | | | |
| DATE : | 19-01-22 | | | | | | |
| TIME COMPLETE : | 1:20 | | | | | | |
| DATE : | 19-01-22 | | | | | | |
| PX-PACKING & FINAL CONTROL | | 36 | 36 | Nil | Nisha(758) Viki(1094) KALI(1078) | Rashni 4:50pm 22/01/22 | NA |
| TIME START : | 4:25 PM | | | | | | |
| DATE : | 22-01-22 | | | | | | |
| TIME COMPLETE : | 4:50 PM | | | | | | |
| DATE : | 22-01-22 | | | | | | |
| SHRINK WRAP | | 5 Box | 5 Box | Nil | FASLI (1054) | Nurin 24/1/22 | 5/5 |
| TIME START : | 10:10 am | | | | | | |
| DATE : | 24-01-22 | | | | | | |
| TIME COMPLETE : | 10:15 am | | | | | | |
| DATE : | 24-01-22 | | | | | | |
| CARTON PACK | | 5 Box | 5 Box | Nil | HERDI (1053) | Nurin 24/1/22 | N/A 24/01/22 |
| TIME START : | 10:10 am | | | | | | |
| DATE : | 24-01-22 | | | | | | |
| TIME COMPLETE : | 10:15 am | | | | | | |
| DATE : | 24-01-22 | | | | | | |

STERILIZATION : ETO

STERILIZATION DATE : 19-01-22

STERILIZATION BATCH NUMBER : ETO220143

FINAL SHIPMENT DATE :

SHIPMENT QUANTITY PCS / CTNS : 30 pcs / 5 Box

COMPLETE/PARTIAL : ☒ COMPLETE ☐ PARTIAL

RETAIN SAMPLE : 1 box (6 pcs)

VMD SAMPLE : N/A

STERILE

Checked by (PR), Signature: [Signature] Name: RATNASEGARAN Date: 26/1/22

Approved by (QA), Signature: [Signature] Name: [Signature] 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. :

Stamp: RELEASED

LABEL PRINTING PROCESS

| PROCESS | | START QTY PCS | OUTPUT PCS | OPERATOR | REJECT PCS | IPQC APPROVAL | REMARKS |
|----------------------|---|------------------|---------------|----------|---------------|------------------|---------|
| PRINTING POUCH LABEL | | | | N/A | | | |
| TIME START : | | | | | | | |
| DATE : | <div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><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| | | | | | |

LABEL APPROVAL

| | | |
|-----------------|---------------|--------------|
| VigiMesh | SIZE : | 6 cm x 11 cm |
| REF | : | RM6110LP |
| LOT | : | A20801 |
| | : | 2027-01 |

VigiMesh™

Polypropylene Mesh.
Knitted. Non-Absorbable.



STERILE EO



Small Pore Light Weight

SIZE: 6cm x 11cm

REF RM6110LP

LOT A20801

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.



STERILE EO



Small Pore Light Weight

SIZE: 6cm x 11cm

QTY : 6 Pcs

REF RM6110LP

LOT A20801

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

LABEL PRINTING CHECKLIST - VIGIMESH

| | | | | |
|-------------|-----------------------|-------------------|-------------|-----------|
| DESCRIPTION | VIGIMESH LP, 6 X 11cm | | | |
| REF | RM6110LP | | INNER POUCH | BOX LABEL |
| LOT NO | A20801 | DATE PRINTED | 15/1/2022 | 15/1/2022 |
| EXP. DATE | 2027-01 | QTY PRINTED (PCS) | 37 | 7 |
| COUNTRY | VMS (MALAYSIA) | PRINTED BY | W501 857 | W501 857 |
| ORDER QTY | 30 + 6 | REMARK | | |

| | | 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 | RM6110LP | <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 | A20801 | <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 :

Poly
15/01/22

Doc. No : PR-LP003
Rev: 0

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

| | |
|---------------------|-------------------|
| Reference / Lot No. | Rm61106p / A20801 |
| Order Quantity | 30 |

A) LASER CUTTING

| No. | Inspection Criteria | Sampling Details | Sample Size | AQL | | Results | | Status (Pass / Fail) |
|-----|--|------------------|-------------|--------|--------|---------|--------|-------------------------|
| | | | | Accept | Reject | Accept | Reject | |
| 1. | Mesh free from burr | 84, 0.4 | 32 | 0 | 1 | 32 | 0 | pass |
| 2. | No contamination | 84, 0.4 | 32 | 0 | 1 | 32 | 0 | pass |
| 3. | No burn marks | 84, 0.4 | 32 | 0 | 1 | 32 | 0 | pass |
| 4. | Edges are well sealed | 84, 0.4 | 32 | 0 | 1 | 32 | 0 | pass |
| 5. | No warping of mesh | 84, 0.4 | 32 | 0 | 1 | 32 | 0 | pass |
| 6. | Dimension (Tolerance: +0.2cm/ -0cm) | 84, 0.4 | 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) |
|----------|--------------------------------------|---|--------------------------------|
| 7/5 | ✓ | ✓ | 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 | ✓ | ✓ | 1.08 | 0.63 | 0.86 | ✓ | ✓ | 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 |
| 6/6 | ✓ | ✓ | Pass |

* Inspection criteria as per Control Plan QCCP-04.

REMARKS: N/A

Inspected By : Boony
Name : Boony
Date : 27/1/2022

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

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

| | | | | | |
|------------------|-------------------------|--|-------------------|--------|---------------|
| Reference Code | Dm61101p | | Lot. No. | A20801 | |
| Item Description | Vigil mesh LP, 6 x 11cm | | Quantity Produced | 36 | 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 | 36 | 0 | 1 | 36 | 0 | pass |
| | Printing is clear and legible | I, 0.15 | 36 | 0 | 1 | 36 | 0 | pass |
| | Correct labeling orientation | I, 0.15 | 36 | 0 | 1 | 36 | 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 | 36 | 0 | 1 | 36 | 0 | pass |

* P= Pass / F=Fail

REMARKS: N/D

Inspected By : Pasit
 Name : PASIT
 Date : 22/01/2022

Verified By : [Signature]
 Name : MARTINI
 Date : 22/01/2022

RAVIMATERIAL LOADING FORM (RMLF)

VIGILENZ®

Doc. No.
Rev.

DATE : 11/01/2022

REF : RM6110LP

LOT NO. : A20801

SHOP PACKET QTY (pcs) : 30

CUSTOMER : VMS (MALAYSIA)

LO NO. : IOVMS/660122/01

RS

6

| NO. | SYSTEM CODE | ITEM DESCRIPTION 1 | DESCRIPTION 2 | LOT NO. | UOM | QUANTITY (pcs) | | | RECEIVED BY |
|-----|-------------|--|---------------|----------|------------|----------------|--------|-------------|-------------|
| | | | | | | REQUIRED | ISSUED | CONSUMPTION | |
| 1 | V0100001 | Surgical Mesh Polypropylene (PPKM 404 ,Light Weight) | VIGIMESH LP | 6X 11 cm | M020210601 | 0.76 | 0.76 | 0.76 | Kanjano |

| (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 | P011200201 | 36 | <i>Tanjana</i> | 1 | P0100371 | Corrugated Carton Box (Part No: ZV07VIGILENZC) - Size: 595 x 375 x 365mm, Printing Plate: P12697 | P100210901 | 1 | <i>meleku</i> |
| 2 | V0100024 | 181mm X 235mm 2FS Uncoated Tyvek Sealed to 12/50 PET/PE | P02C200201 | 36 | <i>Tanjana</i> | 2 | | #N/A | | | |
| 3 | V01000016 | VIGIMESH DISPENSER BOX - SIZE: 245 mm x 15mm x 185mm, MATERIAL: 380gm ARTCARD, 2 COLS + WATERBASE | P108200201 | 541 | <i>Tanjana</i> | 3 | | #N/A | | | |

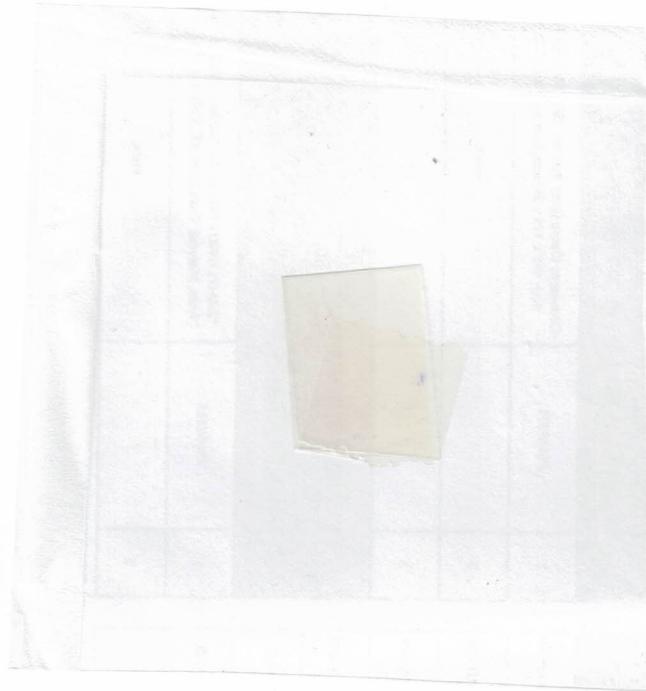
| (4) SPECIAL REQUIREMENT | | | | | | |
|-------------------------|--|-------------|---|---------|--------------------|-------------|
| NO | | SYSTEM CODE | ITEM DESCRIPTION 1 | LOT NO. | QTY REQUIRED (pcs) | RECEIVED BY |
| 1 | | P0100324 | "SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: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

| | | | | | |
|---|----------|---|------------|--------|---------|
| 4 | P0100507 | IF-SB-CNEN-LH Rev. 06, Size: 110mm x 110mm IFU Vigimesh | P070200201 | 5 + 1 | Kanyana |
| 5 | V0100023 | BL00003 - Printed Vigimesh Pouch Label, Size: 130mm x 60mm, Material: MP (New revision) | L120210701 | 42 + 1 | Kanyana |
| 6 | P0100208 | BLANK LABEL (Sharps Pad/ Gauze/ Gd) SIZE: 85mm X 65mm | L190210502 | 5 + 1 | Kanyana |
| 7 | | | #N/A | | |

ISSUED BY (MM) :
Signature :
Name : LOVIN
Date : 11/01/2022

VERIFIED BY (PR) :
Signature :
Name :
Date : 26/1/22

Peel test (2pcs) passed on 19/01/2022



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

| | | |
|-----------------------|-------------------------|--------------------|
| Item Description | Reference No. | Date of Inspection |
| Vigimesh LP, 6x11cm | RM6110LP | 26/01/2022 |
| Sterilization Process | Lot No. | Sample Size |
| ETO | A20801 | 2 pcs |
| | Sterilization Batch No. | Sterilization Date |
| | ET0220143 | 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) | | |
| ✓ | ✓ | ✓ | ✓ | ✓ | 0.77 | | |
| | | | | | 1.30 | | |
| | | | | | 1.04kgf | | |
| | | | | | Pouch Seal Strength (after ETO Sterilization) Min 0.50 kgf Instrument used: 81-02, QC-93 | | |
| | | | | | 1 | 2 | Average |

✓ = Pass X = Fail

CONCLUSION: ☒ RELEASE ☐ ON-HOLD

REMARKS : N/P

Inspected By: Raj
Name : ROSHNI
Date : 26/01/2022

Approved By : [Signature]
Name : A. S. F. W. I.
Date : 26/01/2022

