

**Title: Labels Specifications for NG SI 3X IMT – English**

Reference code: 100120008

Revision.3

Date effective: 14/11/2022

Author name: Ran Amos

<b><u>Approval</u></b> <b>(By electronic signature in Arena BOM Control)</b>	
<b><u>Name</u></b>	<b><u>Position</u></b>
Vladimir Belousov	R&D Director
Mike Besserman	VP, Marketing
Ran Amos	Director of QA/RA

**Revision history**

<b>Date of Change</b>	<b>Change approval reference</b>	<b>The change from previous revision</b>	<b>Revision level</b>
18/08/2021	DCO-003158	Initial document	Rev 0
11/01/2022	DCO-003229	Update labels revision	Rev 1
17/07/2022	DCO-003336	Update labels /PIC/ Carton box (ECO-000102): 1. Implemented EU MDR Requirements for information provided on the device labeling; 2. New ISO 15223-1 2021 symbols were used 3. SING IMT product branding; 4. Manufacturer name was changed to Samsara Vision Ltd. & New logo; 5. Company Web site was updated. 6. Set of "Universal" packaging and Labels .	Rev 2
09/11/2022	DCO-003393	Update labels /PIC/ Carton box (ECO-000108): 1. "Universal" packaging and Labels updated 2. Phone numbers, emails on Patient Implant Cards were updated	Rev 3

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## Labels Specifications for NG SI 3X IMT – English

### PR00118-00

**1. RM01093-02 Rev.2 Patient Implant Card for NG SI (English )**

**SING IMT™ PATIENT IMPLANT CARD**

The bearer of this card has been implanted with an intraocular telescope to improve central vision.

For important Safety Information go to the below website:  
<https://singimt.samsaravision.com>

Alternatively, call Customer Care: +33 (0) 388308812

**MR Conditional.** A patient can be safely scanned with MR under the following conditions:  
Static magnetic field of 1.5 Tesla or 3 Tesla.  
Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 T/m).

 Samsara Vision Ltd.  
21 Yegia Kapayim Street Petah Tikva, 4913020, Israel  
Tel: +972-3-9284000, WEB: [www.samsaravision.com](http://www.samsaravision.com)

 **SAMSARA**  
VISION

Patient name: \_\_\_\_\_ ID: \_\_\_\_\_

Date of implantation: \_\_\_\_/\_\_\_\_/\_\_\_\_ Eye: OS \_\_\_\_ OD \_\_\_\_

Surgeon: \_\_\_\_\_

Healthcare institution: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

Affix File Sticker RM01275-02 here

RM01093-02 REV.02 NOV. 2022

**2. RM01275-02 Rev.0 NG SI IMT 3X File Sticker (English)-Universal**

**MD** SING IMT™ (By Dr. Isaac Lipshitz)

**REF** PR00XXX-00

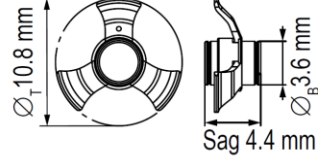
**#** NG SI IMT 3X


**SN** XXXXX-NN


**YY** YYYY-MM-DD

**YY** YYYY-MM-DD

**UDI** (01) 07290018786XXX (17) YYMMDD (11) YYMMDD (21) XXXXXNN



 **SAMSARA**  
VISION



RM01275-02 Rev.00

- RM01092-02 Assembled Patient Implant Card for NG SI (English)**

Item No.	Catalog Number	Description	QTY.
1	RM01093-02	Patient Implant Card for NG SI (English )	1
2	RM01275-02	NG SI IMT 3X File Sticker (English)-Universal	1


**SING IMT™ PATIENT IMPLANT CARD**


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 **SAMSARA**  
VISION

Patient name: \_\_\_\_\_ ID: \_\_\_\_\_

Date of implantation: \_\_\_\_/\_\_\_\_/\_\_\_\_ Eye: OS \_\_\_\_ OD \_\_\_\_

Surgeon: \_\_\_\_\_

Healthcare institution: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

**MD** SING IMT™ (By Dr. Isaac Lipshitz)

**REF** PR00XXX-00


**#** NG SI IMT 3X

**SN** XXXXX-NN

**YY** YYYY-MM-DD

**YY** YYYY-MM-DD

**UDI** (01) 07290018786XXX (17) YYMMDD (11) YYMMDD (21) XXXXXNN



RM01275-02 Rev.00

RM01093-02 REV.02 NOV. 2022

①

②

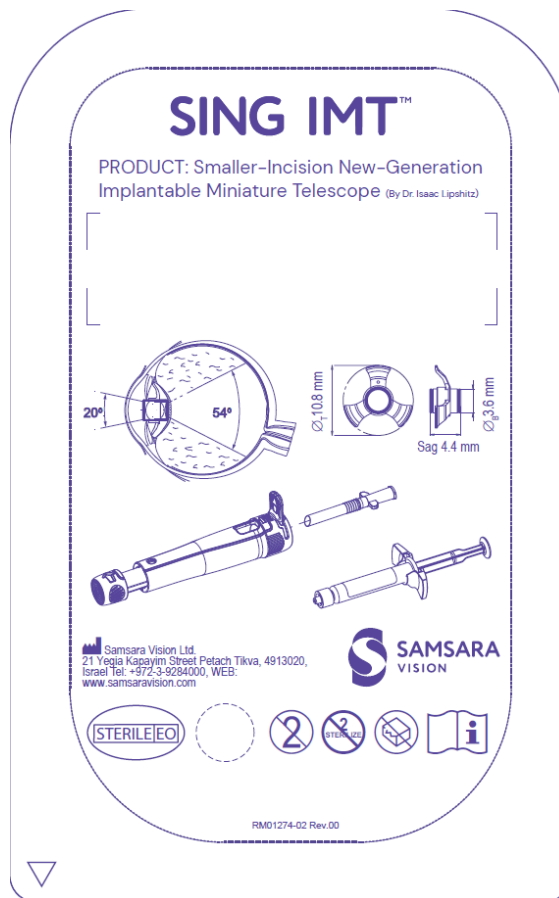
**Title: Labels Specifications for NG SI 3X IMT – English**

Reference code: 100120008

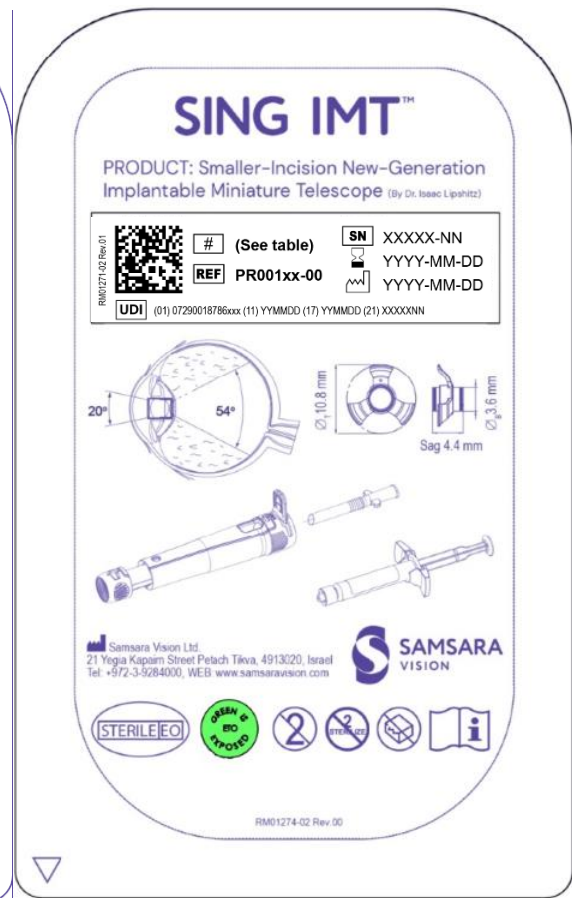
Revision.3

**3. RM01274-02 Rev.0 Printed Tyvek Lid for NG SI (Universal) product (English)**

**NG-SI SBS Before Sterilization**



**NG-SI SBS After Sterilization**




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**4. RM01271-02 Rev.1 NG-SI Tyvek Label 92mm x 25mm (Universal)**

RM01271-02 Rev.01



# (See table)

REF PR001xx-00

SN XXXXX-NN

YYYY-MM-DD

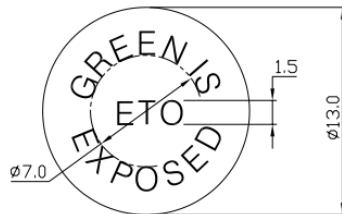
YYYY-MM-DD

UDI (01) 07290018786xxx (11) YYMMDD (17) YYMMDD (21) XXXXXNN

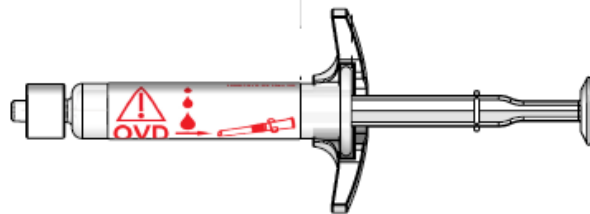
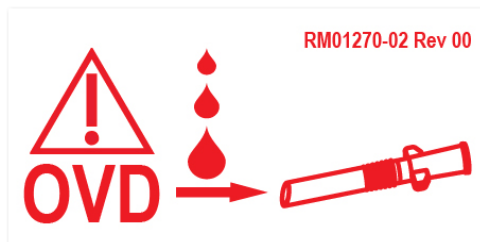
**5. RM01041-02 Rev 03 NG-Si Round SN Sticker**



**6. RM00019-02 STERILIZATION STICKER**



**7. RM01270-02 Rev.0 Syringe Label for NG SI IMT 3X (Universal)**




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**8. RM01272-02 Rev.3 Product detail sticker on WA-Si and NG-Si Carton Box(Universal)**



**SAMSARA**  
VISION

**REF** PR001xx-00


**#** (See table)

**SN** XXXXX-NN

 YYYY-MM-DD

 YYYY-MM-DD

**UDI**





(01) 07290018786xxx (11) YYMMDD (17) YYMMDD (21) XXXXXNN


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(01) 07290018786xxx (11) YYMMDD (17) YYMMDD (21) XXXXXNN

Authorized Representative symbol, name and address  
(See Table)

 0483




**Samsara Vision Ltd.**  
21 Yegia Kapayim Street Petah Tikva, 4913020, Israel  
Tel: +972-3-9284000, WEB: [www.samsaravision.com](http://www.samsaravision.com)

**UDI**

RM01272-02 Rev.03

Product REF	Destination country	Authorized Representative Symbol	Authorized Representative name and address
PR00118-00 PR00121-00 PR00122-00 PR00123-00 PR00124-00 PR00125-00 PR00126-00 PR00127-00 PR00137-00 PR00138-00 PR00139-00 PR00140-00 PR00134-00 PR00141-00 PR00142-00	EU- General, Ireland, Israel EU- Germany, Austria EU- France EU- Italy EU- Spain EU- Portugal EU- Netherland EU- Greece EU- Belgium EU-Poland EU- Norway EU-Romania EU-Turkey EU- Hungary EU-Czech Republic	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">EC</div> <div style="border: 1px solid black; padding: 2px; display: inline-block;">REP</div> </div>	<b>Obelis s.a.</b> Bd. Général Wahis, 53, 1030 Brussels, Belgium Tel: +32 2 732 59 54 E-Mail: <a href="mailto:mail@obelis.net">mail@obelis.net</a> WEB: <a href="http://www.obelis.net">www.obelis.net</a>
PR00118-00	UK	UK RP	<b>Obelis UK LTD.</b> Sandford Gate, Oxford, OX4 6LB, United Kingdom. Phone: +44.1491.378012 E-mail: <a href="mailto:info@obelis.co.uk">info@obelis.co.uk</a>
PR00130-00	Swiss	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">CH</div> <div style="border: 1px solid black; padding: 2px; display: inline-block;">REP</div> </div>	<b>Obelis SWISS GmbH,</b> Ruessenstrasse 12, 6340 Baar/ZG, Switzerland Tel: 041 544 15 26 E-mail: <a href="mailto:Info@obelis.ch">Info@obelis.ch</a>

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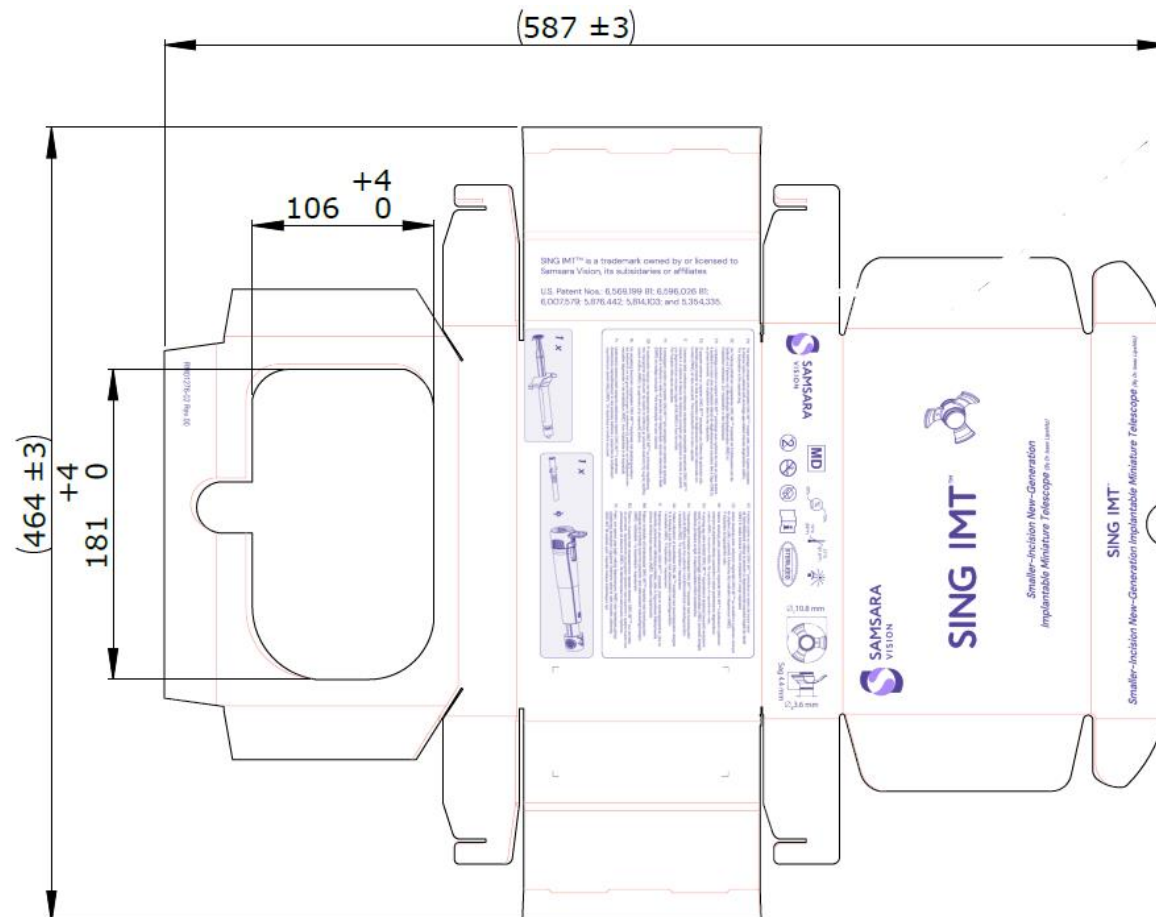
Revision.3

**9. RM01038-02 Rev.9 NG-Si Model Detail Sticker on Single Shipping Package- (Universal)**

	<b>SING IMT™</b> (By Dr. Isaac Lipshitz)		<b>SAMSARA</b> VISION
	<b>PR00XXX-00</b>		
	<b>(See table)</b>		
	<b>XXXXX-NN</b>		
	<b>YYYY-MM-DD</b>		
	<b>YY-MM-DD</b>		
	<b>(01) 07290018786XXX (11) YYMMDD (17) YYMMDD (21) XXXXXNN</b>		
	Samsara Vision Ltd. 21 Yegia Kapayim Street, Petah Tikva, 4913020, Israel Tel: +972-3-9284000, WEB: <a href="http://www.samsaravision.com">www.samsaravision.com</a>		

RM01038-02 Rev.09

**10. RM01276-02 Rev.1 Protective package (carton box) for WA-SI / NG-SI device (Universal)**





## Label Specification

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### 12. RM01035-02 Shipping Container for Single Unit NG-Si Product

ITEM NO.	Catalog Number	DESCRIPTION	Drawing Number	QTY.
1	RM01034-02	Shipping Container for Single Unit Si Product	RD401-52-0001	1
2	PR00118-00	NG SI IMT 3X	RD402-00-0000	1
3	RM01043-02	Shipping Document Pouch 22cm X 11 cm	NA	1
4	RM00579-02	Security Tag	R22-02-1701	1
5	RM00575-02	CE Mark Sticker	R22-02-1602	1
6	RM01045-02	Do Not Freeze Sticker	RD401-52-0005	1
7	RM01038-02	NG-Si Model Detail Sticker (on Single Shipping Package)	RD402-52-0002	1

REVISION RECORD					
REV.	DCO	DESCRIPTION	DRWN.	APPR.	DATE
0	2707	Release of drawing	YOGEV Y.	ELI A.	26.09.18
1	EC073	Addition of model detail sticker	YOGEV Y.	ELI A.	12.10.20

GEN. TOL.	MATERIAL	FINISH	TREATMENT	DRWG.	SIGNATURE	NAME	DATE
±0.1						YOGEV Y.	
±0.05						ELI A.	
±0.05						ELI A.	
±0.05						YULIYA Y.	

PROJECT	WA-SI	HEET NAME	NA
FILE PATH	C:\Users\elias\Documents\Projects\RM01035-01		
DATE	12.10.20		
DRWG. NO.	RD401-52-0000		
REV	1		

### 13. RM01045-02 Do Not Freeze

