

# COMPLIANCE REDLINE REPORT

Label: DRWG107503\_C

Status: NON-COMPLIANT

Score: 36.5%

Passed: 5 | Partial: 10 | Failed: 13

Critical gaps: 18 | New 2024 gaps: 2

## COMPLIANCE GAPS:

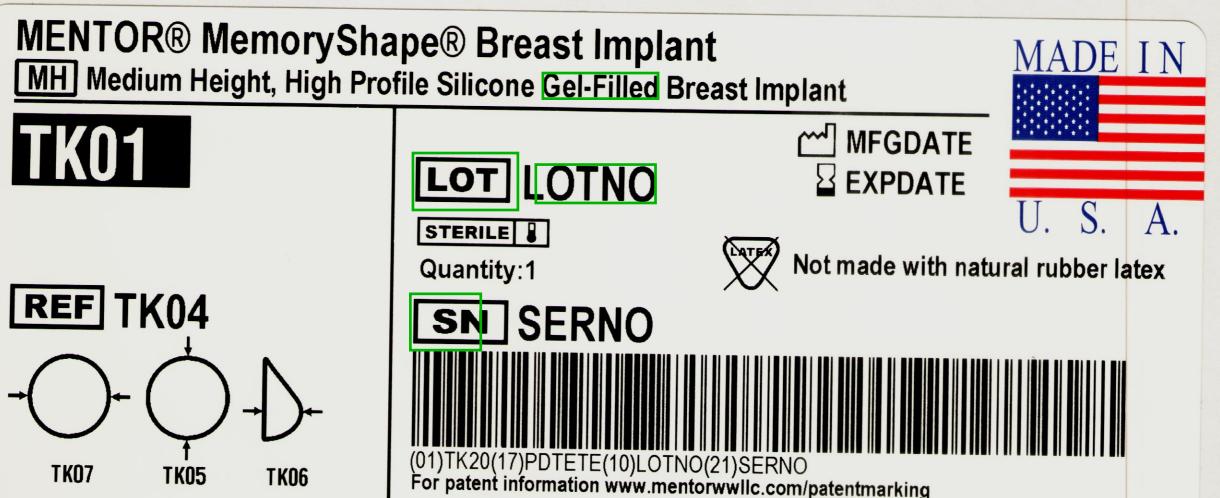
- [CRITICAL] Implant shall be supplied in sealed sterile packaging  
Ref: 9.1
- [CRITICAL] Instructions for use shall accompany the implant  
Ref: 10.1
- [CRITICAL] Labels shall comply with ISO 14630 and ISO 15223-1  
Ref: 11.1
- [CRITICAL] Nominal volume stated on the unit container label  
Ref: 11.2
- [CRITICAL] Implant type/model stated on the unit container  
Ref: 11.2
- [CRITICAL] Implant dimensions: width, height/diameter, projection  
Ref: 11.3 a)
- [CRITICAL] Volume also stated on the implant label (not just container)  
Ref: 11.3 a)
- [CRITICAL] Surface classification per normative Annex G, Table G.2 [NEW 2024]  
Ref: 11.3 c)
- [CRITICAL] Shelf life / use-by date on packaging  
Ref: 11.4
- [CRITICAL] Unique Device Identifier (UDI) on label  
Ref: 11.5
- [CRITICAL] UDI carrier (barcode or 2D DataMatrix)  
Ref: 11.5
- [CRITICAL] Date of manufacture symbol  
Ref: ISO 15223-1:2021, 5.1.3
- [CRITICAL] Use-by date / expiration symbol  
Ref: ISO 15223-1:2021, 5.1.4
- [CRITICAL] Catalogue / reference number symbol  
Ref: ISO 15223-1:2021, 5.1.7
- [CRITICAL] Sterilization method symbol  
Ref: ISO 15223-1:2021, 5.2.1–5.2.8
- [CRITICAL] CE marking with notified body number  
Ref: EU MDR 2017/745, Art. 20

2nd Item Number	Shelf Days	Text Line 01	Text Line 02	Text Line 03	Text Line 04	Text Line 05	Text Line 06	Text Line 07	Text Line 08	Text Line 09	Text Line 10	Text Line 11	Text Line 20
Item Number	Shelf Life	Nom Volume	Max Volume	Diameter	Label Item P/N	Height	Projection	Width	Tolerance	Saline Vol	Gel Volume	Max Projection	GTIN
3340902	1825	165cc	-	-	334-0902	8.5cm	4.6cm	9.0cm	-	-	-	-	00081317005148
3340952	1825	195cc	-	-	334-0952	8.9cm	4.8cm	9.5cm	-	-	-	-	00081317005155
3341002	1825	225cc	-	-	334-1002	9.4cm	5.1cm	10.0cm	-	-	-	-	00081317005162
3341052	1825	260cc	-	-	334-1052	9.9cm	5.3cm	10.5cm	-	-	-	-	00081317005179
3341102	1825	300cc	-	-	334-1102	10.3cm	5.6cm	11.0cm	-	-	-	-	00081317005186
3341152	1825	345cc	-	-	334-1152	10.8cm	5.8cm	11.5cm	-	-	-	-	00081317005193
3341202	1825	390cc	-	-	334-1202	11.3cm	6.0cm	12.0cm	-	-	-	-	00081317005209
3341252	1825	440cc	-	-	334-1252	11.8cm	6.2cm	12.5cm	-	-	-	-	00081317005216
3341302	1825	495cc	-	-	334-1302	12.2cm	6.5cm	13.0cm	-	-	-	-	00081317005223
3341352	1825	555cc	-	-	334-1352	12.7cm	6.7cm	13.5cm	-	-	-	-	00081317005230
3341402	1825	620cc	-	-	334-1402	13.2cm	6.9cm	14.0cm	-	-	-	-	00081317005247
3341452	1825	685cc	-	-	334-1452	13.6cm	7.1cm	14.5cm	-	-	-	-	00081317005254

REVISIONS				
REV	C.O.	DESCRIPTION	DRAWN	DATE
A	15031	RELEASED FOR PRODUCTION	WP	10/15/10
B	PLM	REVISED PER C.O.	WP	SEE PLM
C	PLM	REVISED PER C.O.	WP	SEE PLM



### THERMOFORM LABEL [EART 107503-001]



Patient Name: _____	Patient Name: _____
Surgeon Name: _____	Surgeon Name: _____
Address: _____	Address: _____
Phone Number: ( ) _____	Phone Number: ( ) _____
Date of Implant: _____	Breast: R <input type="checkbox"/> L <input type="checkbox"/>
<b>REF TK04</b>	<b>MENTOR®</b>
<b>LOT</b> <b>LOTNO</b>	3041 Skyway Circle North Irving, TX 75038-3540 USA USA: (800) 235-5731 International: (805) 879-6000
<b>SN SERNO</b>	3041 Skyway Circle North Irving, TX 75038-3540 USA USA: (800) 235-5731 International: (805) 879-6000

MENTOR® MemoryShape® Breast Implant  
**MH** Medium Height, High Profile

TK01 Date of Implant: \_\_\_\_\_ Breast: R  L

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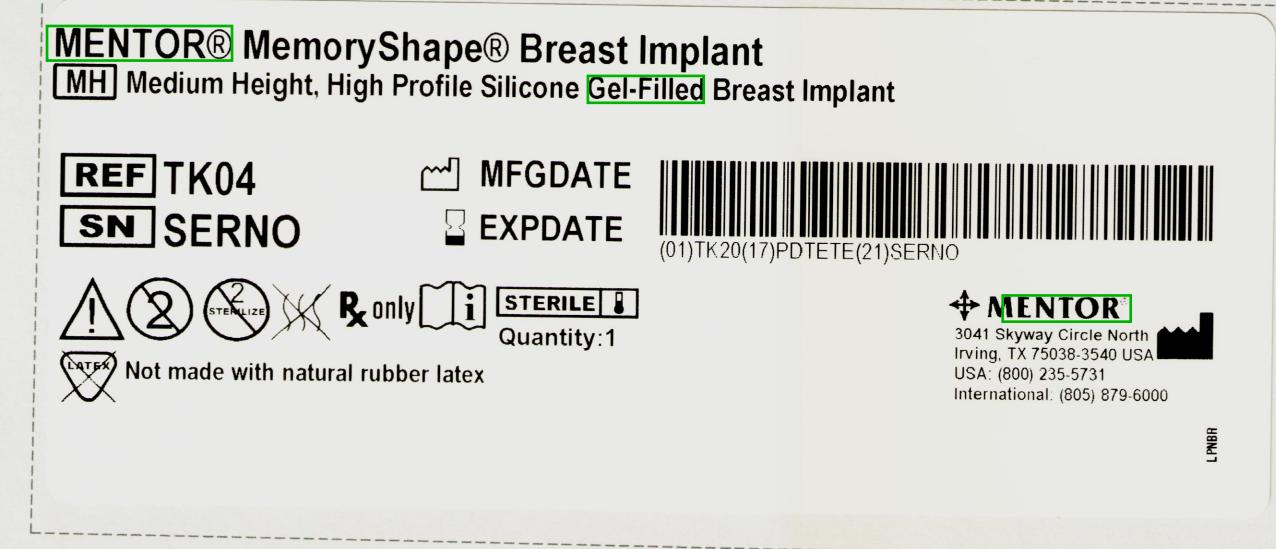
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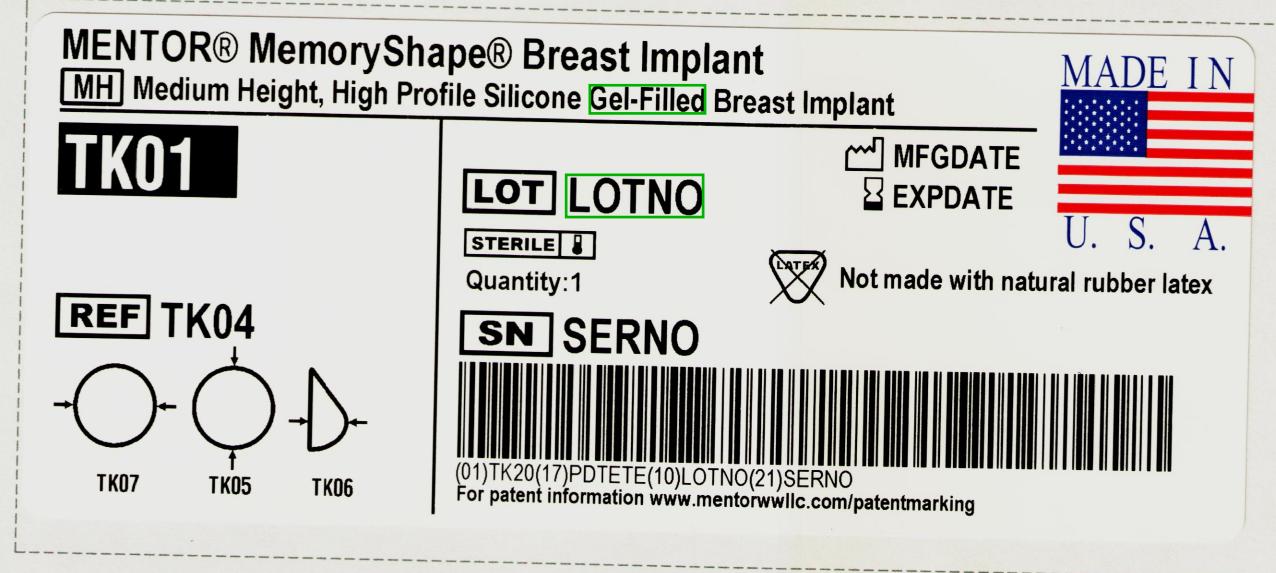
**OUTER LID LABEL  
[EART 107503-010]**



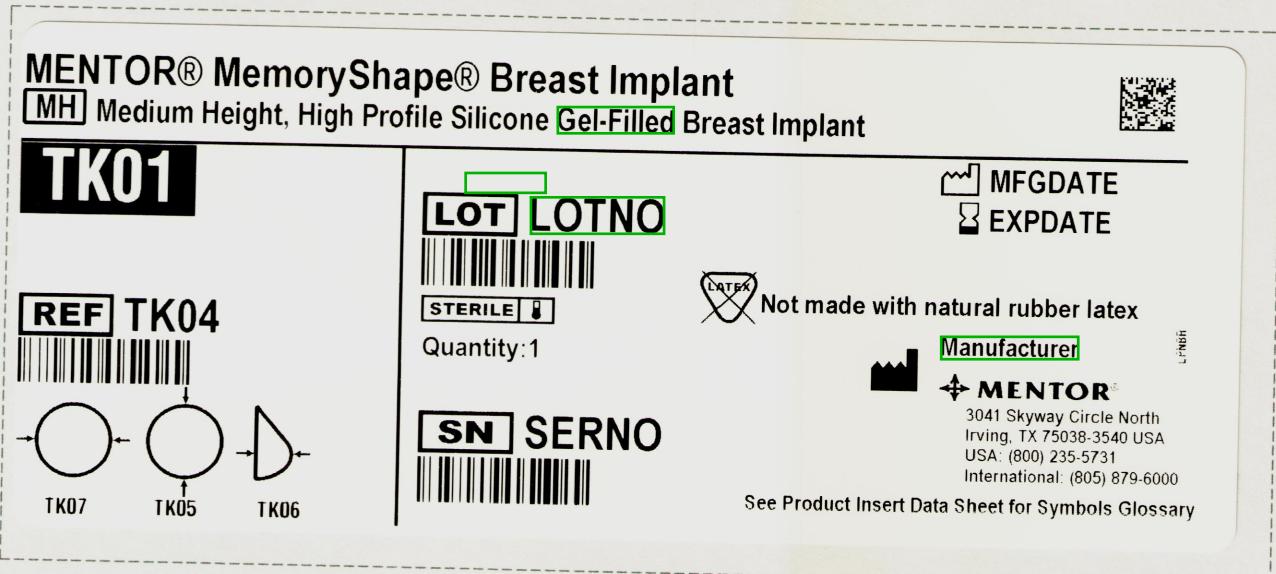
**THERMOFORM LABEL  
[EART 107503-006]**



**CARTON END LABEL  
[EART 107503-007]**



**CARTON END LABEL  
[EART 107503-008]**



**PATIENT RECORD (SET)  
[EART 107503-009]**



Unless otherwise specified, all dimensions are in INCHES and will follow ASME Y14.5M-1994.		<b>MATERIAL</b> ---	<b>MENTOR</b>	
TOLERANCES: DECIMAL: XX = ± .01 XXX = ± .005 XXXX = ± .0005 FRACTIONAL: ± 1/32 ANGULAR: ± 1.0 DEGREES		<b>FINISH</b> ---	TITLE <b>LABELS, GEL, MS, MH, SX</b>	
DRAWN BY: WPAZ DATE: 08/01/14		APPROVED BY: SEE PLM SYSTEM DATE: SEE PLM SYSTEM		SIZE <b>C</b> DRAWING NO. <b>107503</b> REV <b>C</b>
Any deviation from drawing must be submitted to Mentor-Texas for approval		PROJECTION		DO NOT SCALE DRAWING SCALE=1:1 SolidWorks SHEET 2 OF 2 Printed on 3/7/2017
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