

# COMPLIANCE REDLINE REPORT

Label: DRWG107686\_A

Status: NON-COMPLIANT

Score: 49.4%

Passed: 9 | Partial: 8 | Failed: 11

Critical gaps: 13 | New 2024 gaps: 2

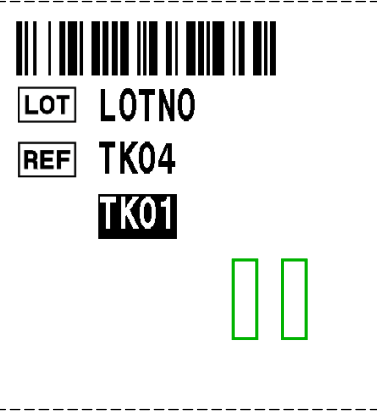
## COMPLIANCE GAPS:

- [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] Implant type/model stated on the unit container  
Ref: 11.2
- [CRITICAL] Surface classification per normative Annex G, Table G.2 [NEW 2024]  
Ref: 11.3 c)
- [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] 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] Manufacturer name and full registered address  
Ref: ISO 14630 / EU MDR Art. 10(11)
- [CRITICAL] GTIN barcode (GS1-128 or 2D DataMatrix)  
Ref: EU MDR / UDI Regulation
- [CRITICAL] Surface classification category code on label [NEW 2024]  
Ref: ISO 14607:2024, Annex G, Table G.2

PROCEDURE PACK										
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 20
-	-	TK01	TK02	TK03	TK04	TK05	TK06	TK07	TK08	TK20
Item Number	Shelf Life	Nom Volume	Max Volume	Diameter	Label Item P/N	Height	Projection	Width	Tolerance	GTIN
3548121	1460	250cc	-	-	354-8121	8.1cm	6.1cm	11.4cm	-	00081317009061
3548122	1460	350cc	-	-	354-8122	9.4cm	6.5cm	12.7cm	-	00081317009078
3548123	1460	450cc	-	-	354-8123	10.2cm	7.1cm	14.0cm	-	00081317009085
3548124	1460	550cc	-	-	354-8124	10.9cm	7.4cm	15.0cm	-	00081317009092
3548125	1460	650cc	-	-	354-8125	11.2cm	7.9cm	15.7cm	-	00081317009108
3548126	1460	750cc	-	-	354-8126	11.9cm	8.1cm	16.5cm	-	00081317009115

DEVICE LEVEL				
2nd Item Number	Shelf Days	Text Line 01	Text Line 04	Text Line 20
-	-	TK01	TK04	TK20
Item Number	Shelf Life	Nom Volume	Label Item P/N DTK04	Device Level GTIN DTK20
3548121D	1460	250cc	354-8121D	10081317030086
3548122D	1460	350cc	354-8122D	10081317030093
3548123D	1460	450cc	354-8123D	10081317030109
3548124D	1460	550cc	354-8124D	10081317030116
3548125D	1460	650cc	354-8125D	10081317030123
3548126D	1460	750cc	354-8126D	10081317030130

DEVICE LEVEL



THERMOFORM LABEL  
[EART 107686-001]

PROCEDURE PACK

DEVICE LEVEL

MENTOR™ CPX™4, Low Height

Breast Tissue Expander, Textured

LH TK01

REF TK04

LOT LOTNO

SN SERNO

(01)TK20(17)EXPDATE(10)LOTNO(21)SERNO

MFGDATE

EXPDATE

STERILE

UDI

MADE IN U.S.A.

MENTOR™ CPX™4, Low Height

Breast Tissue Expander, Textured

LH TK01

REF TK04

LOT LOTNO

SN SERNO

(01)TK20(17)EXPDATE(10)LOTNO(21)SERNO

MFGDATE

EXPDATE

STERILE

UDI

REF DTK04

LOT DLOTNO

SN SERNO

EXPDATE

CE UK CA

MR

UDI

MENTOR™

3041 Skyway Circle North  
Irving, TX 75038-3540 USA  
USA: (800) 235-5731  
International: (805) 879-6000

REF DTK04

LOT DLOTNO

SN SERNO

EXPDATE

CE UK CA

MR

UDI

MENTOR™

3041 Skyway Circle North  
Irving, TX 75038-3540 USA  
USA: (800) 235-5731  
International: (805) 879-6000

REF DTK04

LOT DLOTNO

SN SERNO

EXPDATE

CE UK CA

MR

UDI

MENTOR™

3041 Skyway Circle North  
Irving, TX 75038-3540 USA  
USA: (800) 235-5731  
International: (805) 879-6000

REF DTK04

LOT DLOTNO

SN SERNO

EXPDATE

CE UK CA

MR

UDI

MENTOR™

3041 Skyway Circle North  
Irving, TX 75038-3540 USA  
USA: (800) 235-5731  
International: (805) 879-6000

MENTOR™ CPX™ 4 Tissue Expander, Textured

LH

REF DTK04

SN SERNO

TK01

UDI-DI (01)DTK20

MENTOR™ CPX™ 4 Tissue Expander, Textured

LH

REF DTK04

SN SERNO

TK01

UDI-DI (01)DTK20

MENTOR™ CPX™ 4 Tissue Expander, Textured

LH

REF DTK04

SN SERNO

TK01

UDI-DI (01)DTK20

MENTOR™ CPX™ 4 Tissue Expander, Textured

LH

REF DTK04

SN SERNO

TK01

UDI-DI (01)DTK20

DEVICE LEVEL

MENTOR™ CPX™4, Low Height, Breast Tissue Expander, Textured LH TK01

REF TK04

LOT LOTNO

EXPDATE

STERILE

UDI

MENTOR™

3041 Skyway Circle North  
Irving, TX 75038-3540 USA  
USA: (800) 235-5731  
International: (805) 879-6000

(01)TK20

(17)EXPDATE

(10)LOTNO

CE 2797

UK CA 0086

EC REP

OUTER LID LABEL  
[EART 107686-005]

COMBO LABEL (SET)  
[EART 107686-004]

4. MFG INSPECT PER QCIC000163

3. FIRST ARTICLE INSPECT PER QCIC000001

2. OTHER FIELDS NO. OF MAXIMUM SPACES (CHARACTERS)  
LOTNO = LOT NUMBER 08  
SERNO = SERIAL NUMBER 12  
MFGDATE = MANUFACTURING DATE (YYYY-MM-DD) 10  
EXPDATE = EXPIRATION DATE (YYYY-MM-DD) 10  
LPNBR = LABEL PART NUMBER 10

1. ALL OF THE VARIABLE TEXT IS DISPLAYED AS ITS FIELD NAME.  
THE SPECIFIC DATA TO BE INSERTED INTO THESE FIELDS IS DOCUMENTED  
IN THE MATRIX OF THIS PRINTED LABEL DRAWING.

REVISIONS				
REV	C.O.	DESCRIPTION	DRAWN	DATE
A	PLM	FOR EU-MDR SUBMISSION	JMF	PLM

Unless otherwise specified, all dimensions are in INCHES and will follow ASME Y14.5

TOLERANCES:  
DECIMAL:  
    .XX = ± .01  
    .XXX = ± .005  
    .XXXX = ± .0005  
FRACTIONAL = ± 1/32  
ANGULAR = ± 1.0 DEGREES

Any deviation from drawing must be submitted to Mentor-Texas for approval

PROJECTION

MATERIAL  
N/A

FINISH  
N/A

DRAWN BY:  
J.FIGUEROA

APPROVED BY:  
SEE PLM SYSTEM

DATE:  
01DEC2022

DATE:  
SEE PLM SYSTEM

TITLE  
LABELS, CPX4, LOW, CE\_MARK

SIZE C

DRAWING NO.  
107686

REV  
A

DO NOT SCALE DRAWING

SCALE=1:1

SolidWorks

SHEET 1 OF 1

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