

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



LOT **LOTNO**

REF TK04

TK

THERMOFORM LABEL

[EART 107686-001]

PROCEDURE PACK

MENTOR™ CPX™4, Low Height

COMBO LABEL (SET)

[EART 107686-004]

REVISIONS					
REV	C.O.	DESCRIPTION	DRAWN	DATE	
A	PLM	FOR EU-MDR SUBMISSION	JMF	PLM	
MATERIAL N/A FINISH N/A DRAWN BY: J.FIGUEROA DATE: 01DEC2022 APPROVED BY: SEE PLM SYSTEM DATE: SEE PLM SYSTEM	 TITLE LABELS, CPX4, LOW, CE_MARK				
	SIZE	DRAWING NO.		REV	
	C	107686		A	
	DO NOT SCALE DRAWING		SCALE=1:1	SolidWorks	SHEET 1 OF 1
	PROPRIETARY AND CONFIDENTIAL - THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MENTOR-TEXAS CORP.				