

# COMPLIANCE REDLINE REPORT

Label: ARTW-100765708-01- CPG™ 331 Gel Breast Implant

Status: PARTIAL

Score: 54.6%

Passed: 17 | Partial: 7 | Failed: 15

Critical gaps: 16 | 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] 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] 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] Serial number symbol  
Ref: ISO 15223-1:2021, 5.1.6
- [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] Surface classification category code on label [NEW 2024]  
Ref: ISO 14607:2024, Annex G, Table G.2
- [CRITICAL] Manufacturer — ISO 7000-3082  
Ref: ISO 15223-1:2021, 5.1.1
- [CRITICAL] Authorized representative in the EU  
Ref: ISO 15223-1:2021, 5.1.2
- [CRITICAL] Date of manufacture — ISO 7000-2497  
Ref: ISO 15223-1:2021, 5.1.3
- [CRITICAL] Use-by date — ISO 7000-2607  
Ref: ISO 15223-1:2021, 5.1.4
- [CRITICAL] Sterilized (general symbol)  
Ref: ISO 15223-1:2021, 5.2.1

<div>PREFIX</div> <div>ARTW</div>	DOCUMENT NUMBER: 100765708	REVISION: 1	
TITLE: CPG™ 331 GEL BREAST IMPLANT COHESIVE III, TALL HEIGHT, MODERATE PROFILE			

REVISION:	NAME OF AUTHOR OR CHANGE REQUESTOR:	DESCRIPTION OF THE RELEASE:
Rev 1	K. Fuller	MDR compliant finished <div>device</div> labels containing: <div>GS</div> 128 linear <div>barcode</div> and 2D <div>DataMatrix</div> <div></div>

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TITLE: CPG™ 331 GEL BREAST IMPLANT COHESIVE III, TALL HEIGHT MODERATE PROFILE			Page 1 of 3

Inner label

Outer Lid Label

REF 334-0903

LOT 12345678

SN 12345678-001

125cc

MENTOR™ CPG™ 331  
Gel Breast Implant

REF 334-0903

LOT 12345678

SN 12345678-001

2024-03-02

2029-03-02

(01) 08717694018984

(17) 290302

(21) 12345678-001

125cc

STERILE

MF

Box label

MENTOR™ CPG™ 331 Gel Breast Implant  
Cohesive III, Tall Height, Moderate Profile

125cc

LOT 12345678

SN 12345678-001

2024-03-02

2029-03-02

REF 334-0903

9.0cm 9.2cm 3.2cm

1

STERILE

CE 2797

UK CA 0086

MR


(01)08717694018984 (20)13 (17)290302 (10)12345678 (21)12345678-001

en: CPG™ 331 Gel Breast Implant Cohesive III Tall Height, Moderate Profile  
bg: Гръден имплант със CPG™ 331 гел с голяма височина Cohesive III, среден профил  
cs: Gelový **brsni** implantát CPG™ 331, Cohesive III, vysoká výška, střední profil  
da: CPG™ 331 gelbrystimplantat med høj højde og moderat profil, kohæsivt III  
de: CPG™ 331 Gel-Brustimplantat, Cohesive III, Tall Height, Moderate Profile  
el: CPG™ 331 Εμφύτευση μαστού γέλης Cohesive III υψηλού ύψους, μεσαίας προβολής  
es: Implante mamario CPG™ 331 de gel cohesivo III, altura alta, perfil moderado  
et: Kõrge mõõduka profiiliga sidusa geeliga rinnaimplantaat III CPG™ 331  
fi: Korkea, keskikorkeaprofiilinen geelitäytteenen Cohesive III CPG™ 331 -rintaimplanti  
fr: Prothèse Mammaire CPG™ 331, pré-remplie de gel de silicone, Cohesive III™, Grande Hauteur, Profil Modéré  
hr: Gel-implantat za dojke velike visine i umjerenog profila CPG™ 331 Cohesive III  
hu: CPG™ 331 gél mellimplantátum, kohезív III, nagy magasságú, mérsékelt profilú  
it: Protesi mammaria CPG™ 331 Coesivo III, Altezza alta, Profilo Moderato  
lt: CPG™ 331 silikoninis krūty implantas „Cohesive III“, didelio aukščio, vidutinio profilio  
lv: CPG™ 331 gēla krūts implants Cohesive III, liela augstuma, vidējs profils  
nl: CPG™ 331 gelborstimplantaat cohesieniveau III, hoog model, middelhoog profiel  
no: CPG™ 331 gel-brystimplantat, sammenhengende III, høy høyde, moderat profil  
pl: CPG™ 331, żelowy implant piersi o dużej wysokości Moderate Profile Cohesive III  
pt: Implante mamário de gel CPG™ 331 de perfil moderado e altura elevada Cohesive III  
ro: Implant mamar cu gel CPG™ 331 Cohesive III cu înălțime mare și profil moderat  
sk: CPG™ 331 gellový prsný implantát Cohesive III s vysokou výškou, mierny profil  
sl: Z gelom napolnjen prsni vsadek Cohesive III Tall Height, Moderate Profile CPG™ 331  
sv: CPG™ 331 Gelfyllida Bröstimplantat med höghöjd kohesiv III, måttlig profil  
tr: CPG™ 331 Jel Meme İmplantı Kohesif III Uzun Yükseklik, Orta Profil


(01) 08717694018984 (20) 13  
(17) 290302 (10) 12345678  
(21) 12345678-001


PROPRIETARY & CONFIDENTIAL DOCUMENT





REF	334-0903	 <b>MENTOR</b> Mentor Medical Systems B.V. <u>Leimkestraat</u> 2333 CL Leiden The Netherlands +31 71 7513600
LOT	12345678	
SN	12345678-001	
EXP	2029-03-02	

125cc






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
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



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



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
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**LOT** 12345678  
**SN** 12345678-001  
 2029-03-02  
**125cc**


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 Mentor Medical Systems B.V.  
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 2333 CL Leiden  
 The Netherlands  
 +31 71 7513600


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
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
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
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
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
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CPG™ 331  
Gel Breast Implant

<b>MD</b>	CPG™ 331 Gel Breast Implant			125cc	
<b>MR</b>	<b>REF</b> 334-0903 <b>SN</b> 12345678-001 UDI-DI (01) 08717694018984		<b>UDI</b>		
<b>MD</b>	CPG™ 331 Gel Breast Implant			125cc	
<b>MR</b>	<b>REF</b> 334-0903 <b>SN</b> 12345678-001 UDI-DI (01) 08717694018984		<b>UDI</b>		
<b>MD</b>	CPG™ 331 Gel Breast Implant			125cc	
<b>MR</b>	<b>REF</b> 334-0903 <b>SN</b> 12345678-001 UDI-DI (01) 08717694018984		<b>UDI</b>		



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TITLE: CPG™ 331 GEL BREAST IMPLANT COHESIVE III, TALL HEIGHT, MODERATE PROFILE			Page 2 of 3

Product Information (For Reference Only)

Catalogue Number	GTIN	Vol	Width	Height	Length
334-0903	08717694018984	125 cc	9.0 cm	9.2 cm	3.2 cm
334-0953	08717694018991	150 cc	9.5 cm	9.7 cm	3.3 cm
334-1003	08717694019004	175 cc	10.0 cm	10.2 cm	3.4 cm
334-1053	08717694019011	200 cc	10.5 cm	10.7 cm	3.5 cm
334-1103	08717694019028	230 cc	11.0 cm	11.3 cm	3.6 cm
334-1153	08717694019035	265 cc	11.5 cm	11.8 cm	3.7 cm
334-1203	08717694019042	300 cc	12.0 cm	12.3 cm	3.9 cm
334-1253	08717694019059	340 cc	12.5 cm	12.8 cm	4.0 cm
334-1303	08717694019066	380 cc	13.0 cm	13.3 cm	4.1 cm
334-1353	08717694019073	425 cc	13.5 cm	13.8 cm	4.3 cm
334-1403	08717694019080	475 cc	14.0 cm	14.3 cm	4.5 cm
334-1453	08717694019097	530 cc	14.5 cm	14.8 cm	4.6 cm
334-1503	08717694019103	585 cc	15.0 cm	15.3 cm	4.8 cm
334-1553	08717694019110	645 cc	15.5 cm	15.9 cm	5.0 cm