




MEDIPHACOS EE EMB 14 - Keraring Review 17 Page 1 of 12			
Elaboration: Marco Antônio Lanza 	Review: Aline Freitas 	Approval: Charliane Almeida 	Implementation: date: 2025/04/22

I. REASON FOR REVIEW

Review	Historic	Approval Date
17	Review of items 4.1.5.2 and 4.1.5.3 for label update Change in the paper weight specification of the IFU in item 4.1.11. According to the amendment amendments ID 57/2025 and ID 67/2025. No training is required since the packaging specification has only been updated and everyone receives information regarding the implementation of the document.	Apr 17, 2025
00	Initial issue.	Jan 8, 2019

II. GOAL

Provide the specifications of the packaging and labeling used in the models of the Keraring Intrastromal Corneal Ring product (SI5, SI6, SG, AS5 and AS6) under the scope of the CE marking.

III. SCOPE

This document applies to the Production (Implant Quality and Cleaning - QLI and Packaging), Supply, Logistics and Quality Management and Regulatory Affairs sectors.

IV. TECHNICAL SPECIFICATIONS

4.1. Models and Specifications

4.1.1. Primary packaging

See current version DET IC 14.

4.1.2. 4.1.2. Secondary packaging (sterile barrier)

See current version DET IC 30.

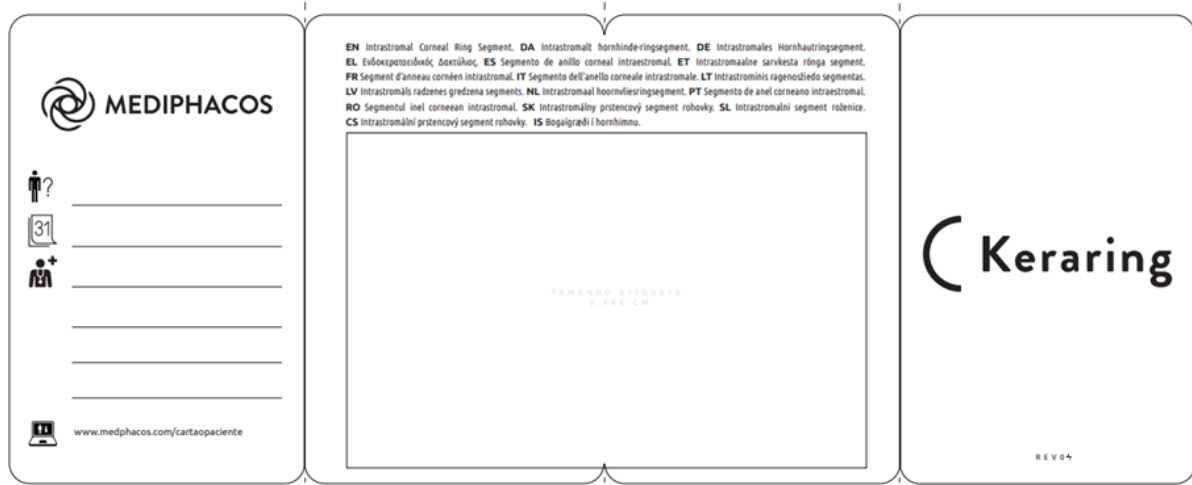
4.1.3. Tertiary packaging:



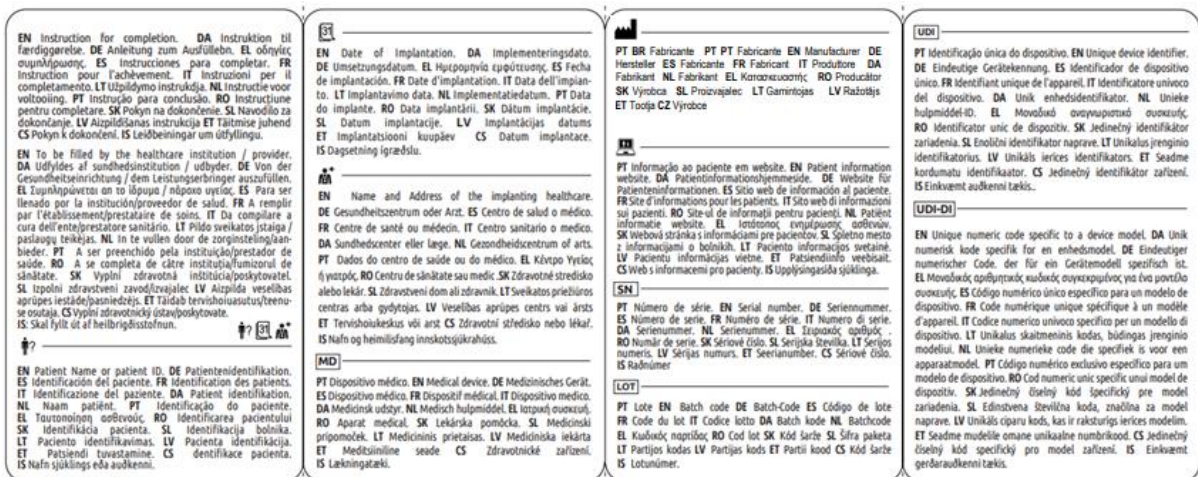
- **Layout:** 200020037 - Keraring Cardboard box Rev 10
- **Dimensions (close):** 96 x 26 x 145 mm
- **Dimensions (open):** 25,5 x 24,0 cm
- **Material:** black ink in lamination and gloss on side 1
- **Grammage:** 325 g
- **Collors:** 3 x 0
- **Pantones:** 8062 C, 7633 C and Black C

4.1.4. Implant card

FRONT



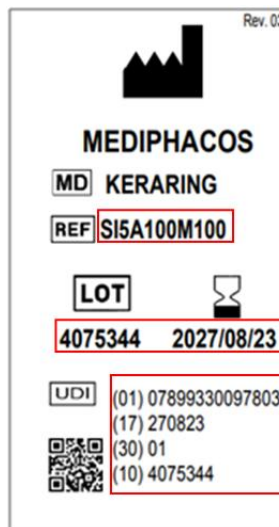
VERSE



- **Layout:** 200050081 Keraring Implant Card Rev 04
- **Dimensions:** 21,2 cm x 8,4 cm
- **Material:** black ink on vitabianco card, gloss lamination
- **Weight:** 325 g (printed double-sided with creases for 03 folds)
- **Pantone:** Black C
- **Disposition:** inserted inside the tertiary packaging (Cardboard box)

4.1.5. Labels

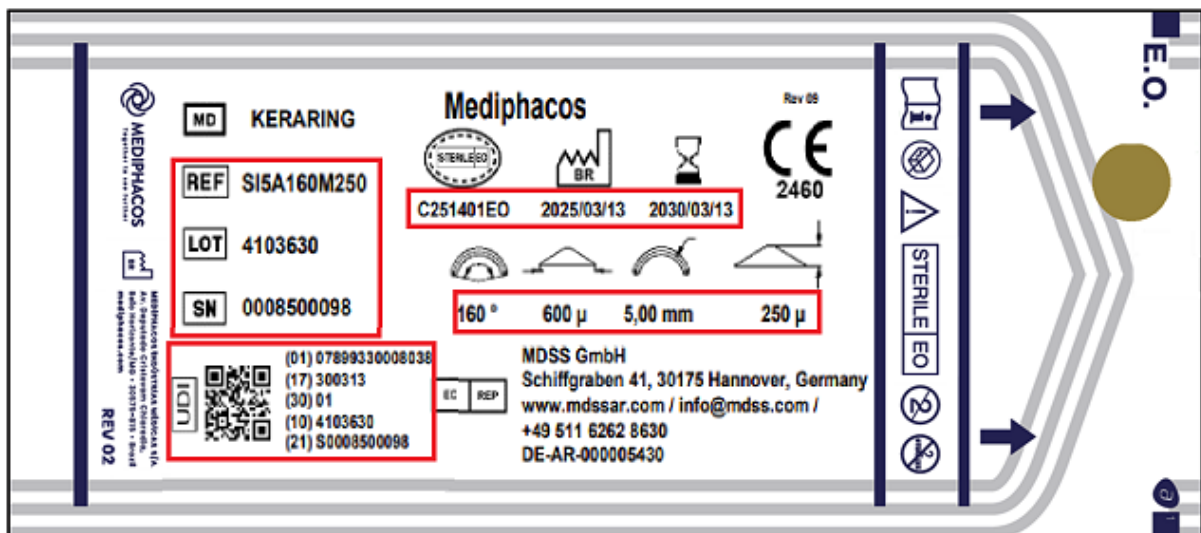
4.1.5.1. Primary packaging label



Variable data: reference, lot (OP), expiration date and UDI

- **Layout:** 200050026 Universal Case Label Rev 03
- **Dimensions:** 44 x 22 mm
- **Material:** couché borracha
- **Disposition:** affixed in the primary packaging (case) of the product.

4.1.5.2. Secondary packaging label



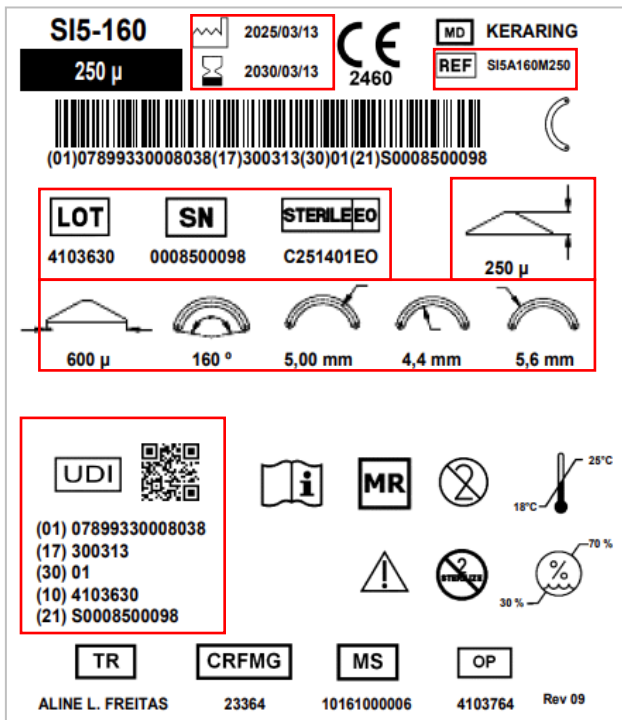
Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

- **Layout:** 200050080 Autofit Especial Padrão UDI 97x220 mm
- **Description:** Keraring identification tag Rev 09
- **Dimensions:** 97 x 220 mm
- **Material:** resin adhesive, transthermic
- **Front material:** 67 to 75 ; 71 micron

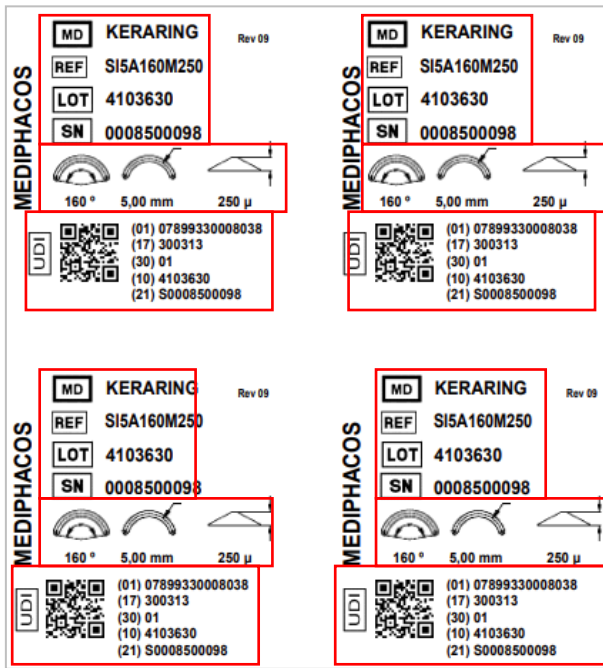
- **Protective material:** 52 to 59; 55.5 g/m²
- **Total weight:** 133 to 150; 141.5 g/m²
- **Total thickness:** 132 to 150; 141 micron
- **Release:** 6 to 14; 180° gf/lin
- **Type of printing:** flexography
- **Varnish:** no
- **Minimum spacing:** 3mm ±1
- **Disposition:** affixed in the secondary packaging (envelope)

4.1.5.3. Tertiary packaging labels:

a) Symmetric models: SI5 and SI6



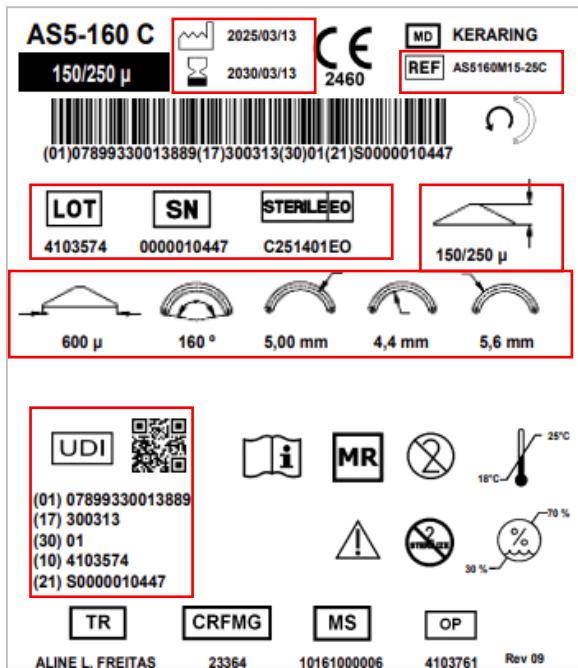
Label affixed to the tertiary packaging (carton/box)



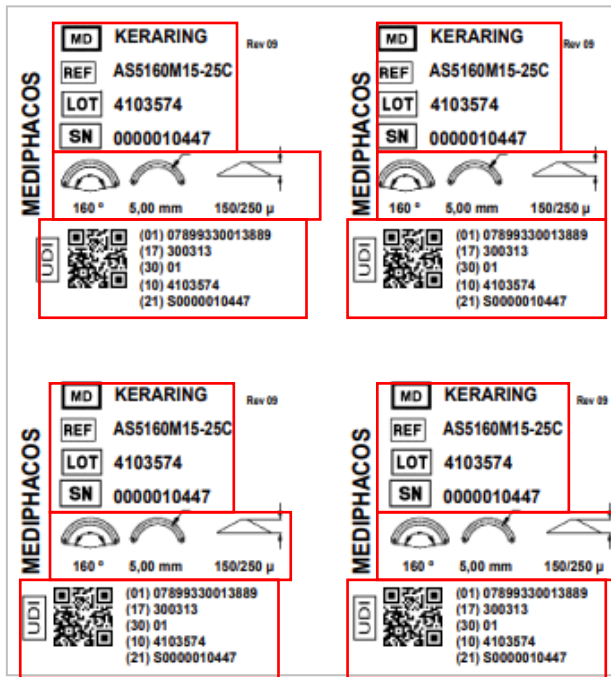
Labels inserted inside the tertiary packaging (carton/box) – 8 units

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

b) Asymmetric models: AS5 and AS6



Label affixed to the tertiary packaging (carton/box)



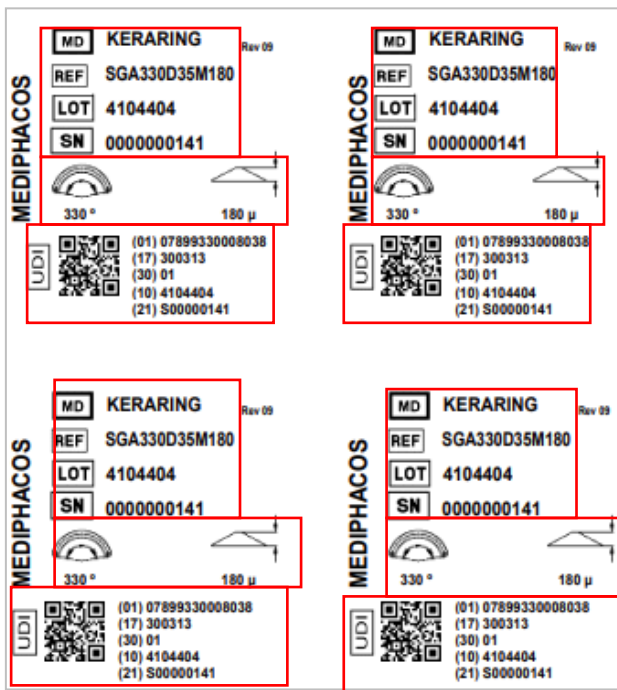
Labels inserted inside the tertiary packaging (carton/box) – 8 units

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications

c) SG Models



Label affixed to the tertiary packaging (carton/box)

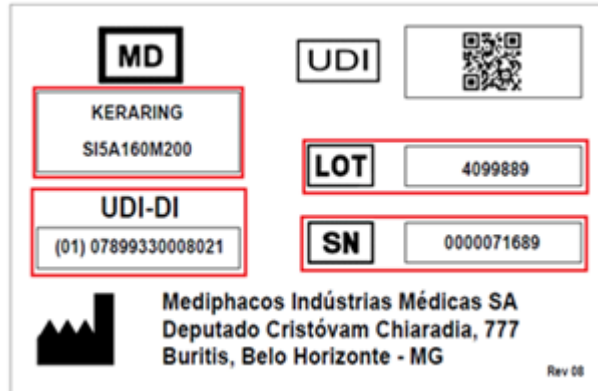


Labels inserted inside the tertiary packaging
(carton/box) – 8 units

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications

- **Layouts:** 200050080 Autofit Especial Padrão UDI 97x220 mm
- **Description:** Keraring identification tag SI Rev 09
Keraring identification tag AS Rev 09
Keraring identification tag SG Rev 09
- **Dimensions:** 97 x 220 mm
- **Material:** resin adhesive, transthermic
- **Front material:** 67 to 75 ; 71 micron
- **Protective material:** 52 to 59; 55.5 g/m²
- **Total weight:** 133 to 150; 141.5 g/m²
- **Total thickness:** 132 to 150; 141 micron
- **Release:** 6 to 14; 180° gf/in
- **Type of printing:** flexography
- **Varnish:** no
- **Minimum spacing:** 3mm ±1

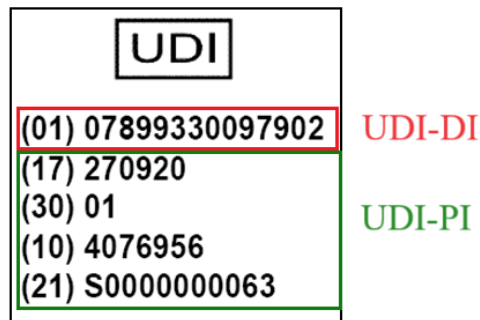
4.1.5.4. Implant card label:



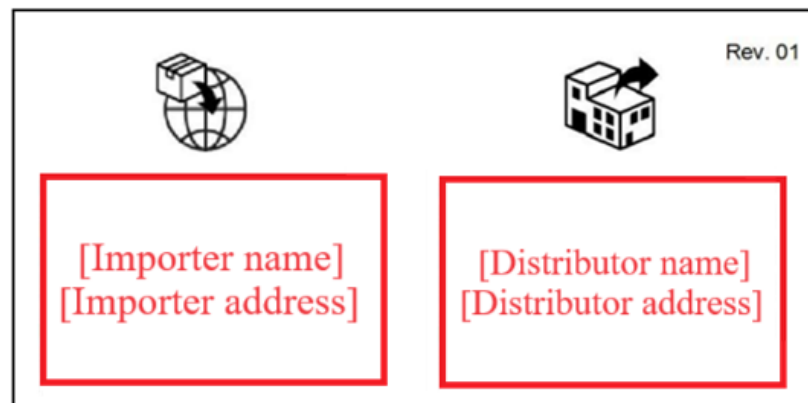
Variable data: reference, lot (OP), UDI-DI and serial number

- **Layout:** 200050080 Autofit Especial Padrão UDI 97x220 mm
- **Description:** Keraring identification tag Rev 09
- **Dimensions:** 9,3 x 6,0 mm
- **Material:** resin adhesive, transthermic
- **Disposition:** affixed to the implant card.

4.1.6. Description of UDI-DI and UDI-PI



4.1.7. Importer and distributor label



Variable data: name and address of the importer and distributor

- **Layout:** 200050085 Etiqueta Import_Distrib Rev 01
- **Dimensions:** 80 x 40 mm
- **Material:** rubber couch
- **Disposition:** affixed by the European Community importer to the tertiary packaging (Cardboard box).

Note 1: If there is any need to change the layout or the information on the label 200050085, the Mediphacos logistics sector, the Mediphacos importer in the European Union and the other importers to which this label applies must be communicated, this communication must be foreseen as an impact on the respective proposed amendment.

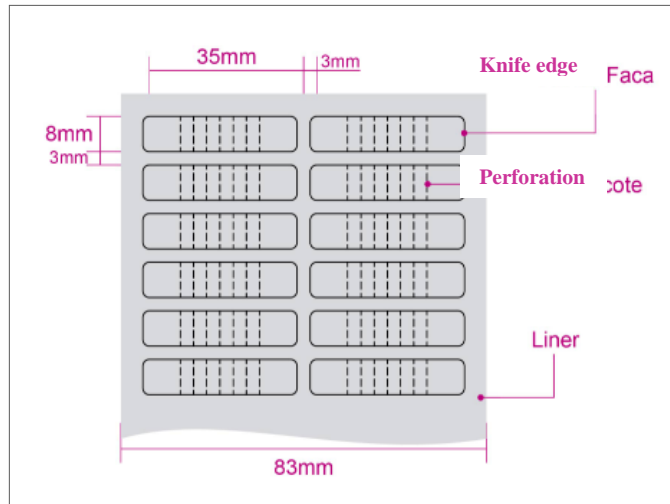
4.1.8. Shipping label

FROM: MEDIPHACOS SA AV. DEPUTADO CRISTOVAM CHIARADIA 840 CNPJ: 21998885/000130 BELO HORIZONTE, 30575-815 - MG BURITIS BRAZIL		1/1
TO: Customer ID: Name: Address: Neighborhood: City: State: Zip Code: Country:		
?	75189	1
ID #: INTERNACIONAL		
		

Variable data: ID code, name, customer address, shipment ID and barcode.

- **Layout:** 900060042 Shipping label
- **Dimensions:** 105 x 138 mm
- **Material:** Coated Paper
- **Adhesive:** Acrylic
- **Arrangement:** Affixed to the product's transport boxes.

4.1.9. Primary packaging security seal



- **Layout:** 200030059 Security Seal Labels for Cases Rev 00
- **Dimensions:** 35,0 x 8,0 mm
- **Material:** bopp transparent, adhesive acrylic
- **Disposition:** affixed to the cover and body of the primary package (case).

4.1.10. Shipping packaging

See current version of EE EMB 17.

4.1.11. Instruction for use:

- **Layout:** 200010006 IFU Keraring Rev 15
- **Dimensions:** 9cm (width) x 13 cm (height)
- **Printing:** 108 pages (27 sheets), Colors 1x1
- **Material:** Coated paper leaflet, 80 g, with folded, intercalated, double-stapled finish, booklet type.
- **Disposition:** inserted in the tertiary package (Cardboard box).

V. ANNEXES

Not applicable.

VI. REFERENCES

ANVISA. Resolution of the Collegiate Board - RDC N 665, of March 30, 2022.

MDR EN ISO 13485:2016_A11:2021 - Medical devices - Quality management systems -Requirements for regulatory purposes.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

ISO 15223-2:2010 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN ISO 20417 2021&LC:2021- Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12).

EN IEC IEEE 82079-1: 2020 (IEC 82079-1: 2019) - Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements

MDCG 2019-8 v2 - Guidance document - Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

MDCG 2021-11 - Guidance on Implant Card - Device types

IPA GQA 08 - Packaging and Marketing Material Control

DET IC 14 - Keraring Case

DET IC 30 Tyvek Surgical Grade Paper Envelope EO 8x18

EE EMB 17 Shipping Boxes