
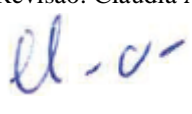



MEDIPHACOS EE EMB 14 - Keraring Revisão 04 Página 1 de 8			
Elaboração: Karine Lima 	Revisão: Cláudia Azevedo 	Aprovação: Marcelo Camargos 	Data: 09/04/2021

I. MOTIVO PARA REVISAO

Revisão	Histórico	Data
04	- Adequação do título do documento e itens II. OBJETIVO e III. ESCOPO. - Alteração do layout do cartucho no item 4.1.5 para o layout com a descrição dos símbolos bilíngues (200020004 Cartucho Keraring Rev 05). Conforme proposta de alteração ID 25/2021	31/03/2021
00	Emissão inicial.	19/12/2019

II. OBJETIVO

Fornecer as especificações das embalagens e rotulagens utilizadas nos modelos do produto anel corneano intraestromal Keraring (SI-5, SI-6, SG, AS-5, AS-6).

III. ESCOPO

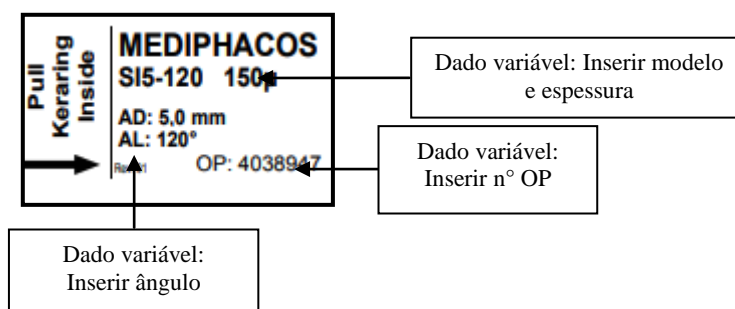
Este documento se aplica aos setores de Qualidade e Limpeza de Implantes (QLI), Embalagem, Suprimentos, Logística e Gerência de Qualidade e Assuntos Regulatórios.

IV. ESPECIFICAÇÕES TÉCNICAS

4.1 Modelos e Especificações

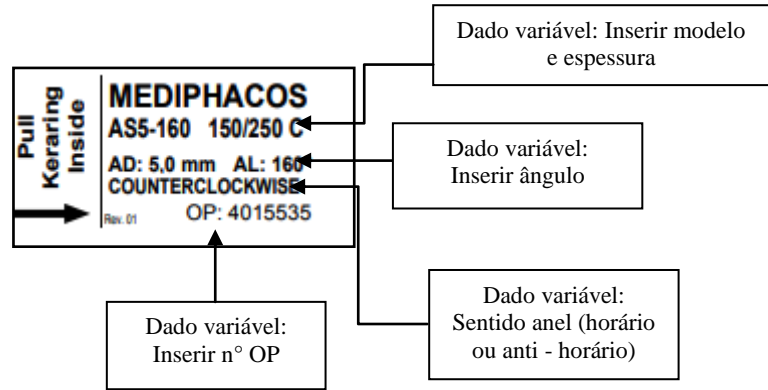
4.1.1 Etiqueta embalagem primária:

4.1.1.1 Anel intraestromal simétrico



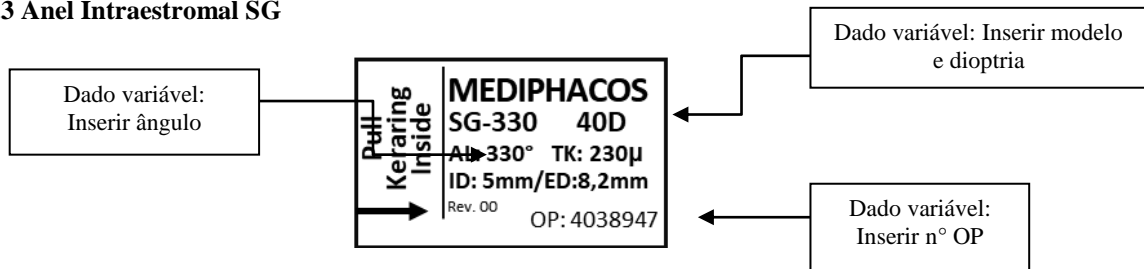
- **Layout:** 200050026 Etiqueta Estojo Universal Keraring Simétrico Rev 01
- **Dimensões:** 44,0 x 22,0 mm
- **Material:** Couche borracha
- **Disposição:** Afixada no estojo.

4.1.1.2 Anel intraestromal assimétrico



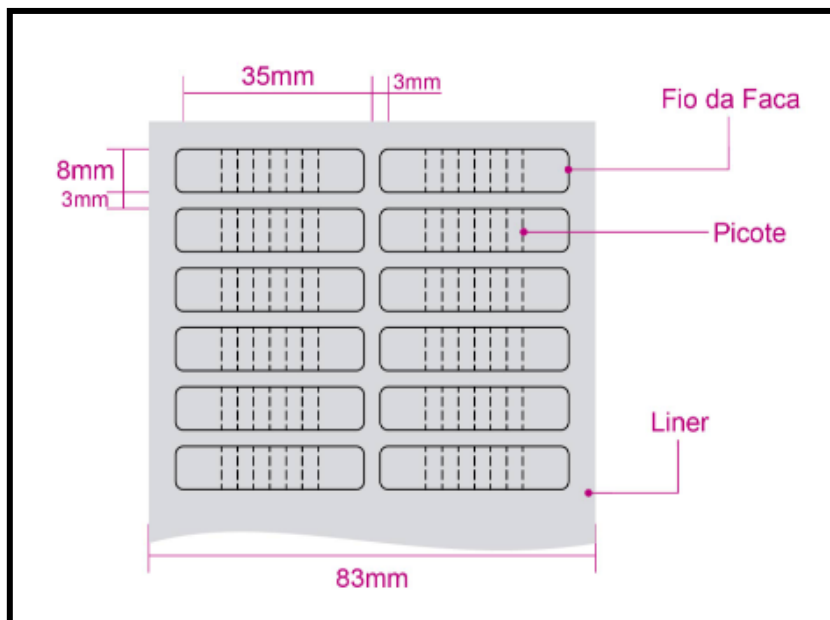
- **Layout:** 200050026 Etiqueta Estojo Universal Keraring Assimétrico Rev 01
- **Dimensões:** 44,0 x 22,0 mm
- **Material:** Couche borracha
- **Disposição:** Afixada no estojo.

4.1.1.3 Anel Intraestromal SG



- **Layout:** 200050026 Etiqueta Estojo Universal Keraring SG Rev 00
- **Dimensões:** 44,0 x 22,0 mm
- **Material:** Couche borracha
- **Disposição:** Afixada no estojo.

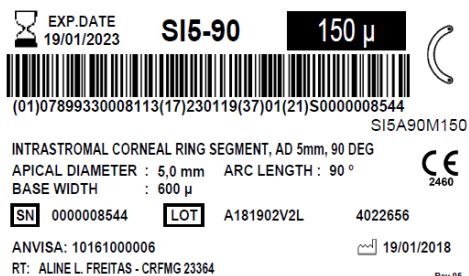
4.1.2 Lacre de segurança de embalagem primária



- **Layout:** 200030059 Etiquetas Lacre de Segurança para Estojos Rev 00
- **Dimensões:** 35,0 x 8,0 mm
- **Material:** Bopp Transparente
- **Adesivo:** Acrílico
- **Disposição:** Afixado na tampa e corpo do estojo, conforme DET IC 35.

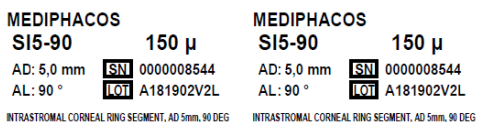
4.1.3 Etiquetas embalagens secundária, final e do paciente:

4.1.3.1 Anel intraestromal simétrico



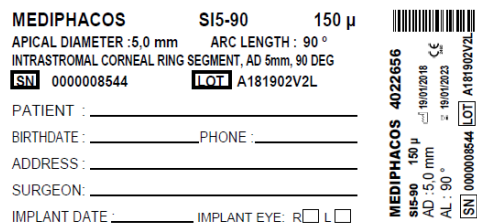
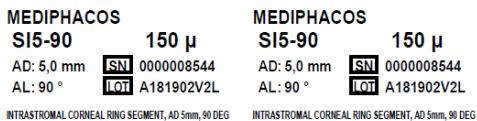
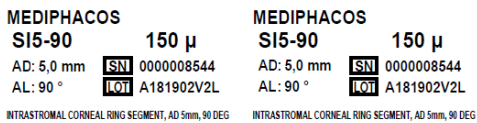
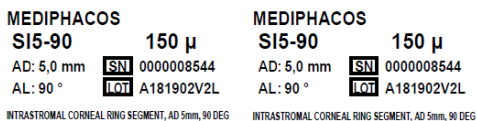
Etiqueta da embalagem final (afixadas no cartucho)

Dados variáveis:
- modelo, espessura e dimensionais do anel;
- lote;
- número de série (SN);
- fabricação e validade.



Etiquetas encaminhadas ao cliente (inseridas no cartucho)

Dados variáveis:
- modelo, espessura e dimensionais do anel;
- lote;
- número de série.



Etiqueta da embalagem secundária (afixadas no envelope)






Dados variáveis:
- modelo, espessura e dimensionais do anel;
- lote;
- número de série;
- data de fabricação e validade.

Etiqueta a ser afixada no cartão do paciente (inserida no cartucho)

Dados variáveis: modelo, espessura e dimensionais do anel, lote e número de série.

- **Layout:** 200050003D Etiquetas Keraring SI Rev 05
- **Dimensões:** 214,0 x 97,0 mm
- **Material:** adesivo resina
- **Disposição:** afixadas na embalagem final (cartucho), inseridas no cartucho, na embalagem secundária (envelope) e a ser afixada no cartão do paciente.



4.1.3.2 Anel intraestromal assimétrico

 EXP. DATE
 19/05/2022 **AS5-160** **150/250 C** 

 (01)07899330013889(17)220519(37)01(21)S0000003418
 AS5160M15-25C
 ASYM RING SEGMENT - COUNTERCLOCKWISE THICKNESS INCREASE 
 APICAL DIAMETER : 5,0 mm ARC LENGTH : 160 °
 BASE WIDTH : 600 µ 150 - 250 µ
SN 0000003418 **LOT** E171901V2L 4015535
 ANVISA: 10161000006  19/05/2017
 RT: ALINE L. FREITAS - CRFMG 23364
Rev 04

Etiqueta da embalagem final (afixadas no cartucho)
 Dados variáveis:
 - modelo, espessura e dimensionais do anel;
 - lote;
 - número de série (SN);
 - fabricação e validade.

<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>	<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>
<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>	<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>
<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>	<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>
<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>	<p>MEDIPHACOS AS5-160 150/250 C AD: 5,0 mm SN 0000003418 AL: 160 ° LOT E171901V2L <small>COUNTERCLOCKWISE</small></p>

Etiquetas encaminhadas ao cliente (inseridas no cartucho)
 Dados variáveis:
 - modelo, espessura e dimensionais do anel;
 - lote;
 - número de série.

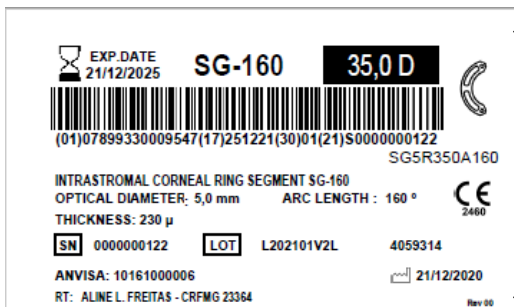
MEDIPHACOS AS5-160 150/250 C
 APICAL DIAMETER : 5,0 mm ARC LENGTH : 160 °
 ASYM RING SEGMENT - COUNTERCLOCKWISE THICKNESS INCREASE
SN 0000003418 **LOT** E171901V2L
 PATIENT : _____
 BIRTHDATE : _____ PHONE : _____
 ADDRESS : _____
 SURGEON : _____
 IMPLANT DATE : _____ IMPLANT EYE: R L

MEDIPHACOS 4015535
 AS5-160 150/250 C 19/05/2017 
 AD : 5,0 mm 19/05/2022
 AL : 160 ° **LOT** E171901V2L **SN** 0000003418

Etiqueta da embalagem secundária (afixadas no envelope)
 Dados variáveis:
 - modelo, espessura e dimensionais do anel;
 - lote;
 - número de série;
 - data de fabricação e validade.

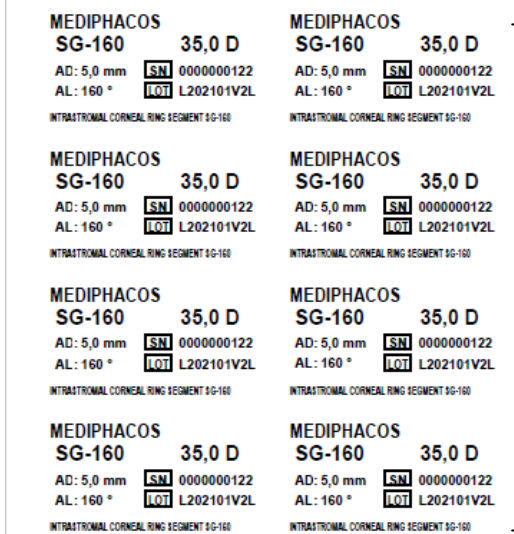
Etiqueta a ser afixada no cartão do paciente
 Dados variáveis: modelo, espessura e dimensionais do anel, lote e número de série.

- **Layout:** 200050003E Etiquetas Keraring AS Rev 04
- **Dimensões:** 214,0 x 97,0 mm
- **Material:** adesivo resina
- **Disposição:** : afixadas na embalagem final (cartucho), inseridas no cartucho, na embalagem secundária (envelope) e a ser afixada no cartão do paciente.

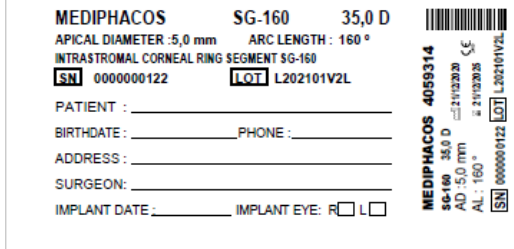
4.1.3.3 Anel intraestromal SG



Etiqueta da embalagem final (afixadas no cartucho)
Dados variáveis:
- modelo, dioptria e dimensionais do anel;
- lote;
- número de série (SN);
- fabricação e validade.



Etiquetas encaminhadas ao cliente (inseridas no cartucho)
Dados variáveis:
- modelo, dioptria e dimensionais do anel;
- lote;
- número de série.



Etiqueta da embalagem secundária (afixadas no envelope)
Dados variáveis:
- modelo, dioptria e dimensionais do anel;
- lote;
- número de série;
- data de fabricação e validade.

Etiqueta a ser afixada no cartão do paciente
Dados variáveis: modelo, dioptria e dimensionais do anel, lote e número de série.

- **Layout:** 200050003L Etiquetas Keraring SG Rev 00
- **Dimensões:** 214,0 x 97,0 mm
- **Material:** adesivo resina
- **Disposição:** afixadas na embalagem final (cartucho), inseridas no cartucho, na embalagem secundária (envelope) e a ser afixada no cartão do paciente.

4.1.4 Cartão do paciente:



- **Layout:** Cartão do Paciente Keraring Rev 03
- **Dimensões:** 80 x 95 mm
- **Material:** tinta preta em cartão vitabianco, 325 g.
- **Laminação:** brilho
- **Disposição:** inserido no cartucho

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4.1.5 Cartucho:



- **Layout:** 200020004 Cartucho Keraring Rev 05
- **Dimensões (fechado):** 96 x 26 x 145 mm
- **Dimensões (aberto):** 25,5 x 24,0 cm
- **Material:** tinta preta em cartão vitabianco, 325 g
- **Cores:** 3 x 0
- **Laminação:** brilho.
- **Pantones:** pantone 8082 M e pantone Black C

4.1.6 Instrução de uso:

- **Layout:** IU Keraring Rev 08
- **Disposição:** inserida no cartucho

V. ANEXOS

Anexo I - EE EMB 14 Keraring (English version)

VI. REFERÊNCIAS

ABNT NBR ISO 13485/2016 - Itens: 4.2.1; 4.2.4 e 4.2.5.

ABNT NBR ISO 15223.1:2015

ANVISA RDC 16/2013 - Item: 5.2.

IPA GQA 08 - Controle de Embalagem e Material de Marketing

IPP EMB 03 - Alocação e Impressão de Etiquetas

DET IC 35 - Lacre de Segurança Estojo Keraring

Anexo I – EE EMB 14 Keraring (English version)

MEDIPHACOS EE EMB 14 - Keraring Revisão 04 Page 1 of 8			
Elaboration: Karine Lima	Review: Cláudia Azevedo	Approval: Marcelo Camargos	Date:

I. REASON FOR REVIEW

Review	Historic	Date
04	- Adequacy of the title of the document and item II. GOAL and III. SCOPE. - Change of the cartridge layout in item 4.1.5 to the layout with the description of the bilingual symbols (200020004 Keraring Rev 05 cartridge).. As proposed for amendment ID 25/2021	31/Mar/2021
00	Initial issue.	08/Jan/2019

II. GOAL

Provide the specifications of the packaging and labeling used in the models of the Keraring intrastromal corneal ring product (SI-5, SI-6, SG, AS-5, AS-6) under the scope of the CE marking.

III. SCOPE

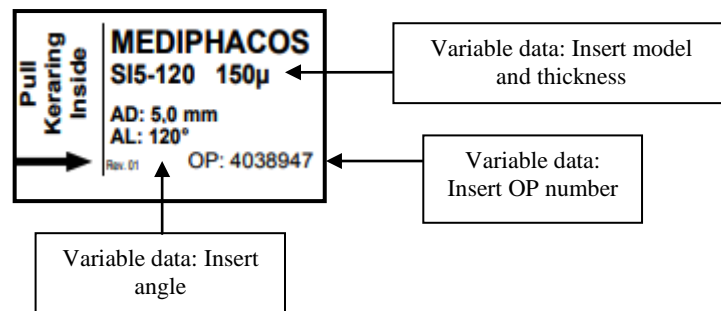
This document applies to the Quality and Cleaning of Implants, Packaging, Supplies, Logistics and Quality Management and Regulatory Affairs sectors.

IV. TECHNICAL SPECIFICATIONS

4.1. Models and Specifications

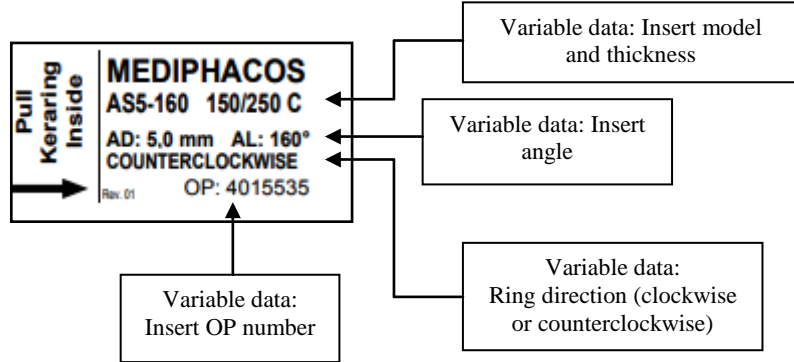
4.1.1. Primary packaging label:

4.1.1.1 Symmetrical intrastromal ring



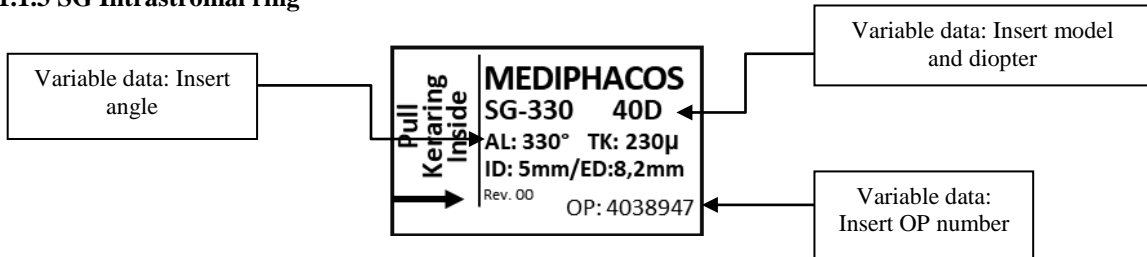
- **Layout:** 200050026 Symmetrical Universal Keraring Case Label Rev 01
- **Dimensions:** 44,0 x 22,0 mm
- **Material:** Rubber couche
- **Disposition:** Affixed to the case.

4.1.1.2 Asymmetrical intrastromal ring



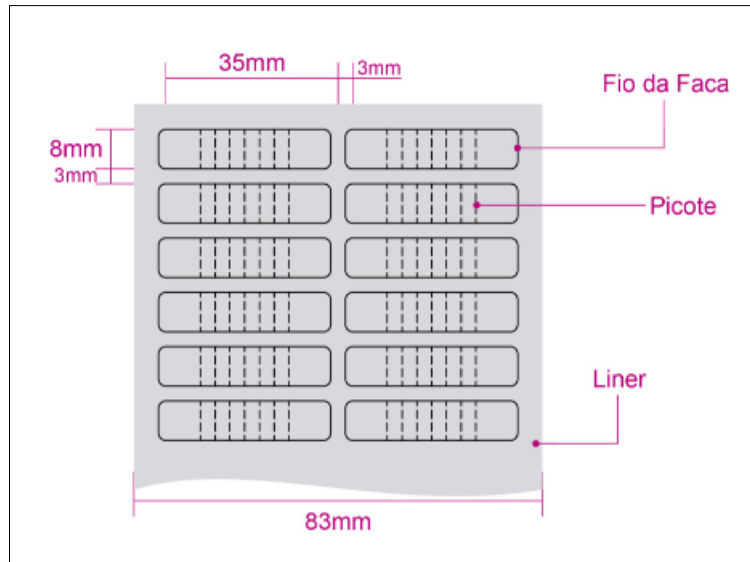
- **Layout:** 200050026 Asymmetric Universal Keraring Case Label Rev 01
- **Dimensions:** 44,0 x 22,0 mm
- **Material:** Rubber couche
- **Disposition:** Affixed to the case.

4.1.1.3 SG Intrastromal ring



- **Layout:** 200050026 Universal Keraring SG Case Label Rev 00
- **Dimensions:** 44,0 x 22,0 mm
- **Material:** Rubber couche
- **Disposition:** Affixed to the case.

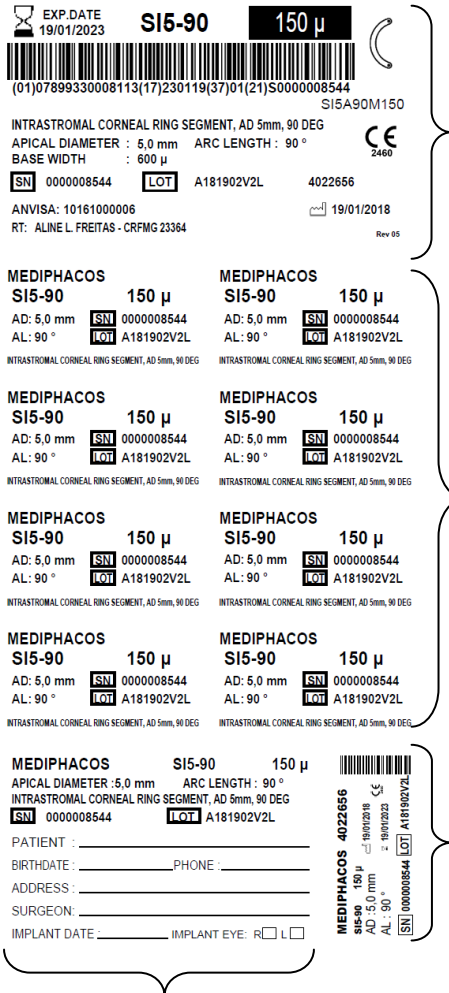
4.1.2. Primary packaging security seal



- **Layout:** 200030059 Security Seal Labels for Cases Rev 00
- **Dimension:** 35,0 x 8,0 mm
- **Material:** Clear Bopp
- **Adesivo:** Acrílico
- **Disposição:** Affixed to the cover and case body, as DET IC 35.

4.1.3. Secondary, final and patient packaging labels:

4.1.3.1 Symmetrical intrastromal ring



Final packaging label (affixed to the cartridge)
Variable data:
- model, thickness and dimensions of the ring;
- batch;
- serial number (SN);
- manufacture and validity.

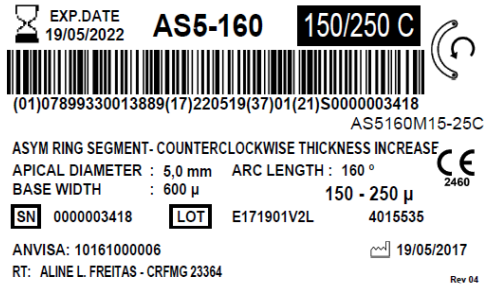
Labels sent to the customer (inserted in the cartridge)
Variable data:
- model, thickness and dimensions of the ring;
- batch;
- serial number.

Secondary packaging label (affixed to the envelope)
Variable data:
- model, thickness and dimensions of the ring;
- batch;
- serial number;
- date of manufacture and validity.

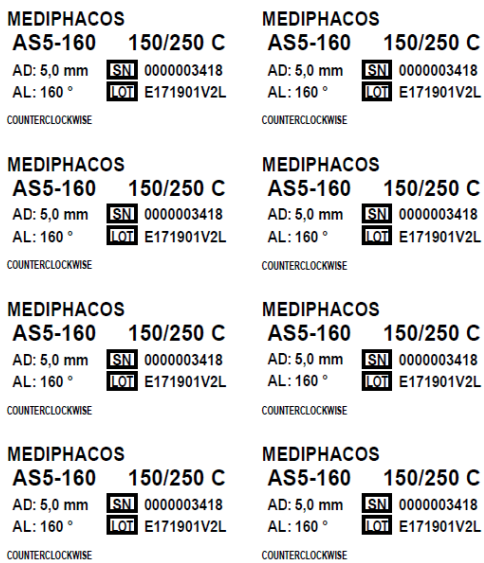
Label to be affixed to the patient's card (inserted in the cartridge)
Variable data: model, thickness and dimensions of the ring, batch and serial number.

- **Layout:** 200050003D Keraring SI labels Rev 05
- **Dimensions:** 214,0 x 97,0 mm
- **Material:** resin adhesive
- **Disposition:** affixed to the final packaging (cartridge), inserted into the cartridge, the secondary packaging (envelope) and to be affixed to the patient's card.

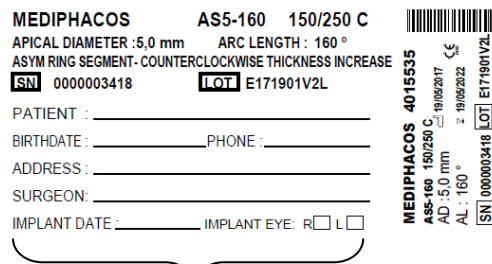
4.1.3.2 Asymmetrical intrastromal ring



Final packaging label (affixed to the cartridge)
 Variable data:
 - model, thickness and dimensions of the ring;
 - batch;
 - serial number (SN);
 - manufacture and validity.



Labels sent to the customer (inserted in the cartridge)
 Variable data:
 - model, thickness and dimensions of the ring;
 - batch;
 - serial number.

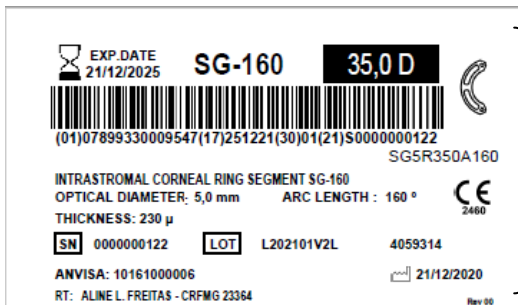


Secondary packaging label (affixed to the envelope)
 Variable data:
 - model, thickness and dimensions of the ring;
 - batch;
 - serial number;
 - date of manufacture and validity.

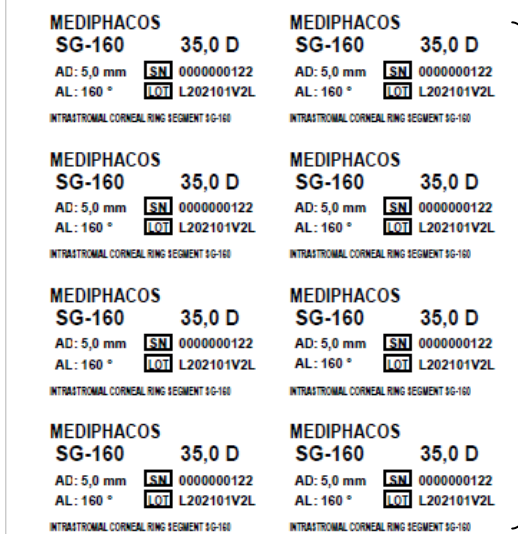
Label to be affixed to the patient's card (inserted in the cartridge)
 Variable data: model, thickness and dimensions of the ring, batch and serial number.

- **Layout:** 200050003E Keraring AS labels Rev 04
- **Dimensions:** 214,0 x 97,0 mm
- **Material:** resin adhesive
- **Disposition:** affixed to the final packaging (cartridge), inserted into the cartridge, the secondary packaging (envelope) and to be affixed to the patient's card.

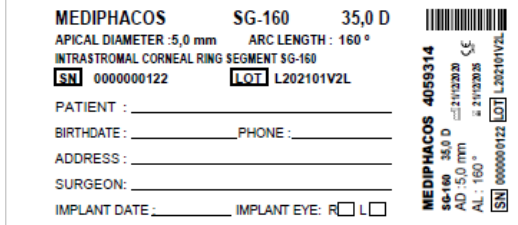
4.1.3.3 Intrastromal ring SG



Final packaging label (affixed to the cartridge)
 Variable data:
 - model, diopter and dimensions of the ring;
 - batch;
 - serial number (SN);
 - manufacture and validity.



Labels sent to the customer (inserted in the cartridge)
 Variable data:
 - model diopter and dimensions of the ring;
 - batch;
 - serial number.



Secondary packaging label (affixed to the envelope)
 Variable data:
 - model, diopter and dimensions of the ring;
 - batch;
 - serial number;
 - date of manufacture and validity.

Label to be affixed to the patient's card (inserted in the cartridge)
 Variable data: model, diopter and dimensions of the ring, batch and serial number.

- **Layout:** 200050003L Keraring SG Labels Rev 00
- **Dimensions:** 214,0 x 97,0 mm
- **Material:** resin adhesive
- **Disposition:** affixed to the final packaging (cartridge), inserted into the cartridge, the secondary packaging (envelope) and to be affixed to the patient's card.

4.1.4. Patient card:



- **Layout:** 200050012 Keraring Patient Card Rev 03
- **Dimensions:** 80 x 95 mm
- **Material:** black ink on vitabianco card, 325 g.
- **Lamination:** shine
- **Disposition:** inserted in the cartridge

4.1.5. Cartridge:



- **Layout:** 200020004 Keraring Cartridge Rev 05
- **Dimensions (closed):** 96 x 26 x 145 mm
- **Dimensions (open):** 25,5 x 24,0 cm
- **Material:** black ink on vitabianco card, 325 g
- **Colors:** 3 x 0
- **Lamination:** shine.
- **Pantones:** pantone 8082 M and pantone Black C

4.1.6. Instruction for use:

- **Layout:** 200010006 IU Keraring Rev 08
- **Disposition:** inserted in the cartridge

V. ANNEXES

Not applicable.

VI. REFERENCES

ABNT NBR ISO 13485/2016 - Itens: 4.2.1; 4.2.4 e 4.2.5.
ABNT NBR ISO 15223.1:2015
ANVISA RDC 16/2013 - Item: 5.2.
IPA GQA 08 - Control of Packaging and Marketing Material
IPP EMB 03 - Label Allocation and Printing
DET IC 35 - Security Seal Labels for Cases Keraring