

MEDIPHACOS EE EMB 14 - Keraring (Modelo CE) Revisão 02 Página 1 de 6			
Elaboração: Maria Clara Almeida <i>Maria Clara Almeida</i>	Revisão: Cláudia Azevedo <i>ll - w</i>	Aprovação: Marcelo Camargos <i>Bruc</i>	Data: 25/06/2020

I. MOTIVO PARA REVISAO

Revisão	Histórico	Data
02	Inclusão dos modelos do Keraring. Não requer treinamento uma vez que o procedimento foi apenas atualizado e todas as áreas recebem um informe sobre a implementação do documento no SQ.	25/06/2020
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) sob escopo da marcação CE.

III. ESCOPO

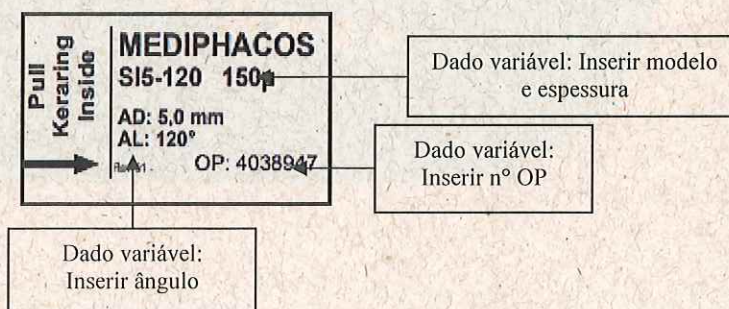
Este documento se aplica aos setores de Qualidade e Limpeza de Implantes, Embalagem, Suprimentos e Gerência de Qualidade e Assuntos Regulatórios.

IV. ESPECIFICAÇÕES TÉCNICAS

4.1 Modelos e Especificações

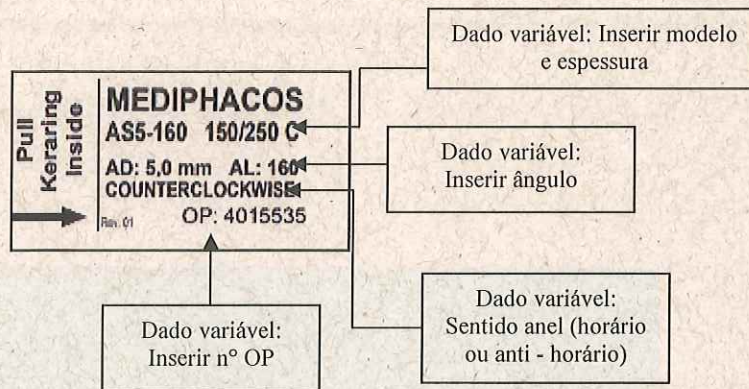
4.1.1 Etiqueta embalagem primária:

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.

4.1.2 Etiquetas embalagens secundária, final e do paciente:

4.1.2.1 Anel intraestromal simétrico

 EXP. DATE
 19/01/2023 **SI5-90** **150 μ** 

 (01)07899330008113(17)230119(37)01(21)S0000008544
 SIS A90M150
 INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG
 APICAL DIAMETER : 5,0 mm ARC LENGTH : 90 °
 BASE WIDTH : 600 μ 
SN 0000008544 **LOT** A181902V2L 4022656
 ANVISA: 10161000006  19/01/2018
 RT: ALINE L. FREITAS - CRFMG 23364 Rev 05

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 SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>	<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>
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Etiquetas encaminhadas ao cliente (inseridas no cartucho)

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

<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>	<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>
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<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>	<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>
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<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>	<p>MEDIPHACOS SI5-90 150 μ AD: 5,0 mm SN 0000008544 AL: 90 ° LOT A181902V2L <small>INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG</small></p>
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MEDIPHACOS **SI5-90** **150 μ**
 APICAL DIAMETER : 5,0 mm ARC LENGTH : 90 °
 INTRASTROMAL CORNEAL RING SEGMENT, AD 5mm, 90 DEG
SN 0000008544 **LOT** A181902V2L
 PATIENT : _____
 BIRTHDATE : _____ PHONE : _____
 ADDRESS : _____
 SURGEON : _____
 IMPLANT DATE : _____ IMPLANT EYE: R L

MEDIPHACOS 4022656
 SI5-90 150 μ
 AD: 5,0 mm
 AL: 90 °
SN 0000008544 **LOT** A181902V2L

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.

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

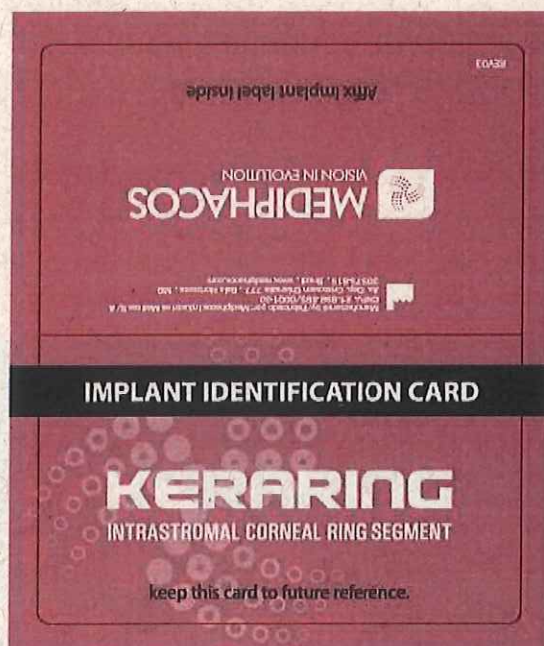
- modelo, espessura e dimensionais do anel;
- lote;
- número de série;
- data de fabricação e validade.

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 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

4.1.4 Cartucho:



- **Layout:** 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

4.1.5 Instrução de uso:

- **Layout:** IU Keraring Rev 07
- **Disposição:** inserida no cartucho

V. ANEXOS

Anexo I – EE EMB 14 Keraring (Model CE)

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

Anexo I – EE EMB 14 Keraring (Model CE)

MEDIPHACOS EE EMB 01 – Keraring (Model CE) Review 02 Page 1 of 6			
Elaboration: Maria Clara Almeida	Review: Cláudia Azevedo	Approval: Marcelo Camargos	Date:

I. REASON FOR REVIEW

Review	Historic	Date
02	Inclusion of Keraring models. It does not require training since the procedure has just been updated and all areas receive a report on the implementation of the document in the SQ.	25/06/2020
00	Initial issue.	08/01/2019

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

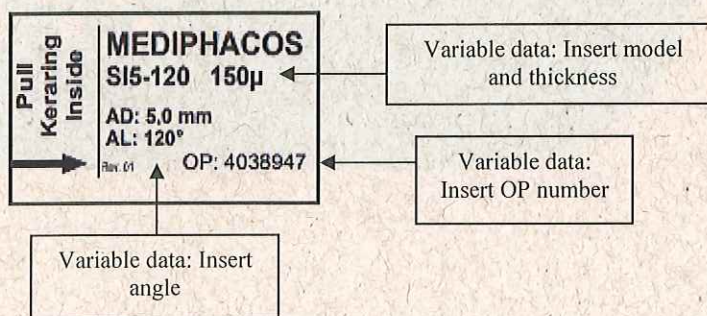
This document applies to the Quality and Cleaning of Implants, Packaging, Supplies and Quality Management and Regulatory Affairs sectors.

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.

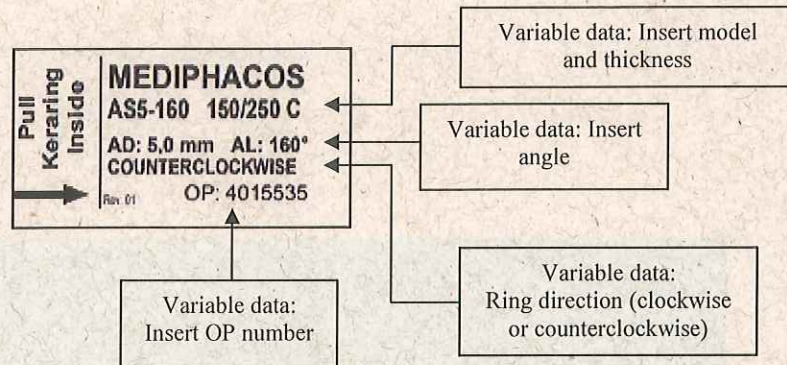
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4.1.1.2 Asymmetrical intrastromal ring



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

4.1.2. Secondary, final and patient packaging labels:

4.1.2.1 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.

4.1.2.2 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

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

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

<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>
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<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>
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<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>
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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 - 19/05/2017
 AL: 160 ° **SN** 0000003418 **LOT** E171901V2L

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.

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4.1.3. 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.

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EE EMB 01 – Keraring (Model CE)

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4.1.4. 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

4.1.5. Instruction for use:

- **Layout:** 200010006 IFU Keraring Rev 07
- **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