DECLARATION OF CONFORMITY
Rev. 12A

We,

Mediphacos Indústrias Médicas S/A
Avenida Deputado Cristóvam Chiarádia, 777. Belo Horizonte, MG, 30575-815. Brazil.
BR-MF-000015743

hereby declare under our sole responsibility that the products, to which this declaration relates, are in conformity with the Essential Requirements Annex I of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC and the transition requirements of the Regulation (EU) 2017/745.

Keraring Intrastromal Corneal Ring Segment
Models: SI5, SI6, SG, AS5 and AS6
Basic UDI DI: 4055724KeraringJJ
UDI DI: UDI DI Code List - Rev. 03 in annex
Certificate Number (MDD 93/42/EEC): 10000341483-PA-NA-BRA Rev. 1.0
Certificate Number (Regulation (EU) 2017/745): Under certification

Intended purpose: Keraring is an Intrastromal Corneal Ring indicated for Keratoconus treatment in the pediatric and adult populations. To be used by surgeons ophthalmologists trained in the Intrastromal Corneal Ring surgical technique. The principle of action of the Intrastromal Corneal Ring is to add mass and volume to the corneal tissue, to reshape its central region towards a flatter and more regular surface. The implantation of the Keraring may be considered in the following cases: Keratoconus in contact lens intolerant patients; Astigmatism following penetrating keratoplasty; Corneal ectasia following Lasik; Pellucid marginal degeneration.

To which this declaration refers, it complies with all provisions of Directive 93/42/EEC as amended by 2007/47/EC that apply to it and with the transition requirements of Regulation (EU) 2017/745. The product is classified as Class IIb, rule8 of Annex IX of the Medical Devices Directive 93/42/EEC and rule 8 of Annex VIII (Chapter III) of Regulation (EU) 2017/745, with the participation of the notified body below informed. The conformity assessment procedure was carried out in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC and Annex XI of Regulation (EU) 2017/745. Furthermore, it is declared that the product referred to in this declaration is not placed on the market with any products that fall within the scope of application of Directive 65/65/EEC.

National and Harmonized Standards applied:

- MDD 93/42/EEC - European Directive - Medical Devices.
- MDR 2017/745 - European Parliament and of the Council of 5 April 2017 - Regulation of Medical Devices.
- Harmonized Standard EN 556-1:2001/AC 2006 (EN 556-1:2001/AC 2006) - Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
- Harmonized Standard EN 556-2:2015 (EN 556-2:2015) - Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
- EN 868-5:2018 - Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
- EN ISO 2233:2001 (ISO 2233:2000) - Packaging Complete, filled transport packages and unit loads - Conditioning for testing
- EN 22248:1992 (ISO 2248:1985) - Packaging - Complete, filled transport packages - Vertical impact test by dropping
- EN ISO 8318:2002 (ISO 8318:2000) - Packaging - Complete, filled transport packages and unit loads - Sinusoidal vibration tests using a variable frequency
- Harmonized Standard EN ISO 10993-1:2009/AC:2010 (ISO 10993-1:2009/AC:2010) / EN ISO 10993-1:2020 (ISO 10993-1:2018) - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

- EN ISO 10993-2:2022 (ISO 10993-2:2022) - Biological evaluation of medical devices - Part 2: Animal welfare requirement
- Harmonized Standard EN ISO 10993-3:2014 (ISO 10993-3:2014) - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Harmonized Standard EN ISO 10993-5:2009 (ISO 10993-5:2009) - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Harmonized Standard ISO 10993-6:2009 (ISO 10993-6:2007) / EN ISO 10993-6:2016 (ISO 10993-6:2016) - Biological evaluation of medical devices - parte 6: Tests for local effects after implantation
- Harmonized Standard EN ISO 10993-7:2008/AC:2009 (ISO 10993-7:2008/Cor 1:2009) / EN ISO 10993-7:2008/AMD 1:2022 (ISO 10993-7:2008/AMD 1:2019) - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals. Amendment 1: Applicability of allowable limits for neonates and infants
- MDR Harmonized Standard EN ISO 10993-9:2021 (ISO 10993-9:2019) - Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
- MDR Harmonized Standard EN ISO 10993-10:2023 (ISO 10993-10:2021) / ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Harmonized Standard EN ISO 10993-11:2018 (ISO 10993-11:2017) - Biological evaluation of medical devices - Parte 11: Tests for systemic toxicity
- MDR Harmonized Standard EN ISO 10993-12:2021 (ISO 10993-12:2021) - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- Harmonized Standard EN ISO 10993-13:2010 (ISO 10993-13:2010) - Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
- EN ISO 10993-16:2017 (ISO 10993-16:2017) - Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
- Harmonized Standard EN ISO 10993-17:2009 (ISO 10993-17:2002) - Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- Harmonized Standard EN ISO 10993-18:2009 (ISO 10993-18:2005) / EN ISO 10993-18:2020 (ISO 10993-18:2020/AMD 1:2022) - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- MDR Harmonized Standard EN ISO 10993-23:2021 (ISO 10993-23:2021) - Biological evaluation of medical devices - Part 23: Testes for Irritation
- ISO/TR 10993-33:2015 Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3
- MDR Harmonized Standard EN ISO 11135:2014/A1:2019 (ISO 11135:2014/A1:2018) - Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- Harmonized Standard EN ISO 11138-2:2009 (ISO 11138-2:2006) / EN ISO 11138-2:2017 (ISO 11138-2:2017) - Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization
- Harmonized Standard EN ISO 11140-1:2009 (ISO 11140-1:2005) / EN ISO 11140-1:2014 (ISO 11140-1:2014) - Sterilization of health care products - Chemical indicators - Part 1: General requirements
- EN ISO 11357-1:2023 (ISO 11357-1:2023) / ISO 11357-1:2023 - Plastics - Differential scanning calorimetry (DSC) - Part 1: General principles
- Harmonized Standard EN ISO 11607-1:2009 (ISO 11607-1:2006) / EN ISO 11607-1:2020/A11:2022 (ISO 11607-1:2019)- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- Harmonized Standard EN ISO 11607-2:2006 (ISO 11607-2:2006) / EN ISO 11607-2:2020/A11:2022 (ISO 11607-2:2019) - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- MDR Harmonized Standard EN ISO 11737-1:2018/A1:2021 (ISO 11737-1:2018/A1:2021) - Sterilization of medical devices - Microbiological methods - Part 1: Determination of population of microorganisms on products.
- MDR Harmonized Standard EN ISO 11737-2:2020 (ISO 11737-2:2019) - Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- EN ISO 11979-6:2014 (ISO 11979-6:2014) - Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing
- EN 13018:2016 - Non-Destructive Testing - Visual Testing - General Principles European Pharmacopoeia
- MDR Harmonized Standard EN ISO 13485:2016/A11:2021 (ISO 13485:2016) - Quality management Systems - Medical devices - requirements for regulatory purposes.

- Harmonized Standard EN ISO 14155:2011/AC:2011 (ISO 14155:2011) / EN ISO 14155:2020 (ISO 14155:2020) - Clinical investigation of medical devices for human subjects - Good clinical practice.
- Harmonized Standard EN ISO 14630:2009 (ISO 14630:2008) / EN ISO 14630:2012 (ISO/DIS 14630:2012) - Non-active surgical implants - General requirements
- EN ISO 14644-1:2015 (ISO 14644-1:2015) - Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
- EN ISO 14644-2:2015 (ISO 14644-2:2015) - Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
- EN ISO 14644-3:2019 (ISO 14644-3:2019) - Cleanrooms and associated controlled environments - Part 3: Test methods
- EN ISO 14644-4:2022 (ISO 14644-4:2022) - Cleanrooms and associated controlled environments Part 4: Design, construction and start-up
- EN ISO 14644-5:2004 (ISO 14644-5:2004) - Cleanrooms and associated controlled environments - Part 5: Operations
- EN ISO 14644-7:2004 (ISO 14644-7:2004) - Cleanrooms and associated controlled environments- Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
- EN ISO 14644-9:2022 (ISO 14644-9:2022) - Cleanrooms and associated controlled environments - Assessment of surface cleanliness for particle concentration
- EN ISO 14644-10:2022 (ISO 14644-10:2022) - Cleanrooms and associated controlled environments-- Part 10: Classification of surface cleanliness by chemical contamination
- Harmonized Standard EN ISO 14937:2009 (ISO 14937:2009) - Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- MDR Harmonized Standard EN ISO 14971:2019/A11:2021 (ISO 14971:2019) - Medical Device - application of risk management to medical devices
- MDR Harmonized Standard EN ISO 15223-1:2021 (ISO 15223-1:2021) - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- ISO 16142-1:2016 - Medical devices - Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
- CEN ISO/TS 16775:2021 (ISO/TS 16775:2021) - Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2
- EN 17141:2020 - Cleanrooms and associated controlled environments - Biocontamination control
- CEN ISO/TR 20416:2020 (ISO/TR 20416:2020) - Medical devices - Post-market surveillance for manufacturers
- EN ISO 20417:2021/LC 2021 (ISO 20417:2021) / ISO 20417:2021 - Medical devices - Information to be supplied by the manufacturer
- ISO/TS 21726:2019 - Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
- CEN ISO/TR 24971:2020 (ISO/TR 24971:2020) - Medical Devices - Guidance on the Application of ISO 14971
- Harmonized Standard EN 62366:2008 (ISO 62366:2007) / EN 62366-1:2015/AMD 1:2020 (IEC 62366-1:2015/AMD 1:2020) - Medical devices - Part 1: Application of usability engineering to medical devices
- EN IEC/IEEE 82079-1:2020 (IEC/IEEE 82079-1:2019) - Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements
- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing Practice
- ASTM D6361/D6361M-98 (2020) - Guide for Selecting Cleaning Agents and Processes
- ASTM F1929-15 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980-21 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2847-17 - Standard Practice for Reporting and assessment of residues on single-use implants and single-use sterile instruments
- ASTM F3127-22 - Standard Guide for Validating cleaning processes used during the manufacture of medical devices
- ASTM F88/F88M-21 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM G122-20 - Standard Test Method for Evaluating the Effectiveness of Cleaning Agents
- ASTM G131-96(2023)^{e1} - Standard Practice for Cleaning of Materials and Components by Ultrasonic Techniques
- MDCG 2018-1 Rev. 4 - Guidance on BASIC UDI-DI and changes to UDI-DI

- MDCG 2018-2 - Future EU medical device nomenclature - Description of requirements
- MDCG 2018-6 - Clarifications of UDI related responsibilities in relation to article 16
- MDCG 2018-7 - Provisional considerations regarding language issues associated with the UDI database
- MDCG 2019-1 - MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG 2019-4 - Timelines for registration of device data elements in EUDAMED
- MDCG 2019-5 - Registration of legacy devices in EUDAMED
- MDCG 2019-7 - Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)
- 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 2019-9 Rev.1 - Summary of safety and clinical performance
- MDCG 2020 - Joint Implementation/preparedness plan on the new Medical Devices Regulation 2017/745 (MDR)
- MDCG 2020-3 Rev. 01 - Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
- MDCG 2020-5 - Clinical Evaluation - Equivalence
- MDCG 2020-6 - Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
- MDCG 2020-7 - Post-market clinical follow-up (PMCF) Plan Template
- MDCG 2020-8 - Post-market clinical follow-up (PMCF) Evaluation Report Template
- MDCG 2020-10/1 Rev 01 - Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745
- MDCG 2020-10/2 - Clinical investigations Summary Safety Report Form v.1.0
- MDCG 2020-13 - Clinical Evaluation Assessment Report Template
- MDCG 2020-15 - MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
- MDCG 2021-1 Rev.1 - Guidance on harmonized administrative practices and alternative technical solutions until EUDAMED is fully functional
- MDCG 2021-5 Guidance on standardization for medical devices
- MDCG 2021-6 - Regulation (EU) 2017/745 - Questions & Answers regarding clinical investigation
- MDCG 2021-10 - The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
- MDCG 2021-11 - Guidance on Implant Card - Device types
- MDCG 2021-12 - FAQ on the European Medical Device Nomenclature (EMDN)
- MDCG 2021-19 - Guidance note integration of the UDI within an organization's quality management system
- MDCG 2021-20 - Instructions for generating CIV-ID for MDR Clinical Investigations
- MDCG 2021-25 - Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
- MDCG 2021-26 - Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- MDCG 2021-27 - Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- MDCG 2021-28 - Substantial modification of clinical investigation under Medical Device Regulation
- MDCG 2022-7 - Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- MDCG 2022-11 - Notice to manufacturers to ensure timely compliance with MDR requirements
- MDCG 2022-16 - Guidance on Authorized Representative Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
- MDCG 2022-18 ADD 1 - MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate
- MDCG 2022-21 - Guidance on periodic safety update report (PSUR) according to regulation (EU) 2017/745 (MDR)
- MDCG 2023-1 - Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and regulation (EU) 2017/746
- MDCG 2023-3 - Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices
- MEDDEV 2.7.1 rev. 04 - Guidelines on medical devices - Clinical Evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
- MEDDEV 2.12.1 Rev. 08 - Guidelines on a medical devices vigilance system

- MEDDEV 2.12.2 Rev. 02 - Guidance document Medical devices - Market surveillance - Post Market Clinical Follow-up studies
- Regulation (EU) 2016/679 - European Parliament and of the Council of 27 April 2016.
- Blue Guide on the implementation of EU product rules 2022.
- RDC 665, March 30th, 2022 - Good Manufacturing Practices for Medical Devices - ANVISA (Brazilian Law)
- RDC 546, August 30th, 2021 - Essential safety and efficacy requirements for medical products - ANVISA (Brazilian Law)

Notified Body: DNV Product Assurance AS,
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European representative: Medical Device Safety Service GmBH (MDSS)
Schiffgraben 41, 30175 Hannover, Germany
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Belo Horizonte, August 08th, 2023.

Cláudia Gomes Azevedo
Person Responsible for Regulatory Compliance
Mediphacos Indústrias Médicas S/A

Emyr Francisco Soares Jr.
AdministrativeDirector/Partner
Mediphacos Indústrias Médicas S/A

REVISON HISTORY

Revision	History	Date
12	Inclusion of the standards MDR Harmonized Standard MDR Harmonized Standard EN ISO 10993-10:2023 (ISO 10993-10:2021), EN ISO 11357-1:2023 (ISO 11357-1:2023) / ISO 11357-1:2023, MDCG 2023-1, MDCG 2023-3, MDCG 2020-3 Rev 01, MDCG 2022-18 ADD 1, ASTM G131-96(2023)e1. Withdraw the standard ISO 10993-10:2013 (ISO 10993-10:2010), EN ISO 11357-1:2016 (ISO 11357-1:2016), MDCG 2020-3, MDCG 2022-18, ASTM G131-96(2016)e1.	2023/08/08
11	Updating of the version of UDI DI List from Rev. 02 to Rev. 03.	2023/03/30
10	Inclusion of the Basic UDI DI. UDI DI Code List version updating. Updating the Harmonized Standard EN ISO 11607-1:2009 (ISO 11607-1:2006) / EN ISO 11607-1:2020 (ISO 11607-1:2019) to Harmonized Standard EN ISO 11607-1:2009 (ISO 11607-1:2006) / EN ISO 11607-1:2020/A11:2022 (ISO 11607-1:2019), Harmonized Standard EN ISO 11607-2:2009 (ISO 11607-2:2006) / EN ISO 11607-2:2020 (ISO 11607-2:2019) to Harmonized Standard EN ISO 11607-2:2009 (ISO 11607-2:2006) / EN ISO 11607-2:2020/A11:2022 (ISO 11607-2:2019) and EN ISO 14644-4:2001 (ISO 14644-4:2001) to EN ISO 14644-4:2022 (ISO 14644-4:2022). Updating the address of Notified Body from Veritasveien3, N-1363 Høvik, Norway to Veritasveien1, N-1363 Høvik, Norway.	2022/11/01
09	Inclusion of the product intended purpose, declaration that the products are in conformity of the transition requirements of the Regulation (EU) 2017/745, the rule of risk classification and conformity assessment according Regulation (EU) 2017/745, MDD 93/42 Certificate Number, the signature of the Person Responsible for Regulatory Compliance, the ISO 10993-18:2020/AMD 1:2022standard and the Blue Guide on the implementation of EU product rules 2022. Updating of the version of UDI DI List from Rev. 00 to Rev. 01.	2022/08/02

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Revision	History	Date
08	Inclusion of MDR Harmonized Standard EN ISO 11737-1:2018/AMD,MDR Harmonized Standard EN ISO 10993-9:2021, MDR Harmonized Standard EN ISO 13485:2016/A11:2021, MDR Harmonized Standard EN ISO 14971:2019/A11:2021, MDR Harmonized Standard EN ISO 10993-12:2021 (ISO 10993-12:2021), EN ISO 11737-1:2018/A1:2021, MDR Harmonized Standard EN ISO 15223-1:2021 (ISO 15223-1:2021), CEN ISO/TR 20416:2020, EN ISO 20417:2021/C:2021 and RDC 665, March 30th, 2022. Withdraw of Decision 2021/1182. Inclusion of the UDI DI Code List - Rev. 00 as reference of UDI DI. Inclusion of the registration number in EUDAMED of the actors Manufacturer and Authorized Representative. Update of the name of the notified body according to the name of the actor present in EUDAMED. Update of dates of History Review in YYYY/MM/DD format.	2022/05/25
07	Inclusion of the standard EN ISO 10993-9:2021(ISO 10993-9:2019).	2022/02/08
06	Inclusion of the standards MDR Harmonized Standard EN ISO 10993-23:2021 (ISO 10993-23:2021), MDR Harmonized Standard EN ISO 11135:2014 (ISO 11135:2014/AMD 1:2019), RDC 546, August 30, 2021, Regulation (EU) 2016/679, Decision No. 1182 of July 19, 2021.	2022/01/20
05	Update of dates of History Review in MM-DD-YYYY format. Inclusion of the standard ISO/TR 20416/2020 and the European Regulation 2017/745.	2021/09/17
04	The document was reviewed to update the standards version.	2020/09/21
03	The document was reviewed to update the standards.	2019/05/07
02	The document was reviewed to include the statement of which the manufacturer is exclusively responsible for the declaration of conformity.	2019/06/06
01	The document was reviewed to include the Revisions History.	2021/04/01