Hydroxypropyl Methylcellulose Ophthalmic Solution 2% w/v (HPMC) – iVistaVida 2%

iVistaVida is clear isotonic solution, contains Hydroxypropyl Methylcellulose USP 20mg / ml concentration. It is high retention and dispersive viscoelastic solution which is widely used for phacoemulsification / cataract surgery. iVistaVida's unique properties offers good space maintenance and excellent tissue protection throughout the procedure.

iVista Vida has low molecular weight, less surface tension and it is Non-Antigenic.

Viscosity at Rest	: 4000 – 5000 mPas / 5000 – 7000 mPas
pH	: 6.8 – 7.6
Osmolality	: 270– 400 mOsm/Kg
Raw Material	: Non-Animal Origin
Packing Material	: Premium Quality of Pharmaceutical Grade

Available in 2ml PFS & 3ml PFS

Hydroxypropyl Methylcellulose Ophthalmic Solution 2.4% w/v (HPMC) – iVistaVida 2.4%

iVistaVida 2.4% is clear isotonic solution, contains Hydroxypropyl Methylcellulose USP 24mg / ml concentration. It is high retention and dispersive viscoelastic solution which is widely used for phacoemulsification / cataract surgery. iVistaVida's unique properties offers good space maintenance and excellent tissue protection throughout the procedure.

iVista Vida 2.4% has low molecular weight, less surface tension and it is Non-Antigenic.

Viscosity at Rest	: 5000 –10000 mPas
pH	: 6.8 – 7.6
Osmolality	: 270– 400 mOsm/Kg
Raw Material	: Non-Animal Origin
Packing Material	: Premium Quality of Pharmaceutical Grade

Available in 2ml PFS & 3ml PFS

Sodium Hyaluronate Ophthalmic Solution 1% w/v – iOcuVida 1%

iOcuVida 1% is intended for use during surgery in the anterior and posterior segments of the human eye. It is designed to create and maintain anterior chamber depth and visibility, protect corneal endothelial cells and other intraocular tissues, minimize interaction between tissues during surgical manipulation. Also preserves tissue integrity and good visibility when used to fill the anterior and posterior segment of eye.

Procedures include:-
. Cataract extraction
. Intraocular lens (IOL) implantation
. Corneal transplantation surgery
. Glaucoma filtering surgery.

Advantage:-
.BD Glass Syringe
.Imported Viscoelastic Cannula
.Blister Packing
.Imported EP Grade API
.No refrigeration required - Store at Room Temp

Molecular Weight	: 2.8 Million Dalton
Viscosity at Rest	: upto 310000 mPas
pH	: 6.8 – 7.6
Osmolality	: 270– 400 mOsm/Kg
Raw Material	: Non-Animal Origin
Packing Material	: Premium Quality of Pharmaceutical Grade

Available in 1ml PFS, 1.5ml PFS, 1.6ml PFS, 1.8ml PFS & 2ml PFS

CERTIFICATE

This is to certify that

HEIL PHARMA

Main Office:
FF-114, Shayona Center, Next to Shayona Estate, Near Memco Cross Road, Memco, Ahmedabad - 380 025, Gujarat, India.

Conforms to the requirements of the Management System Standard

ISO 13485:2016

Medical Quality Management System

For the following scope

- **Manufacturing of Medical Device such as Ophthalmic Surgical Aids and Surgical Disposables, Balanced Salt Solution, Sterile Viscoelastic Solution for Ophthalmic, Osteoarthritis and Dermal**

Certificate No: **CL/A/09/MDQMS**

Approval Date	: **22/03/2019**
Valid Until	: **21/03/2021**

CLEPIER LIMITED

Authorized Signatory
For CLEPIER LTD.

Scan the QR code for current status and authenticity of the certificate

Global Euro Accreditation Centre GEAC Global Euro Accreditation Centre

Accreditation Registration Number: PAC-GEAC-1812-102

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Heil Pharma

FF-114 Shayona Centre,
Next to Shayona Estate,
Near Memco Cross Road,
Memco, Ahmedabad – 380025
Gujarat, India

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2% w/v 2ml PFS, 3mlPFS	Class IIb
Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2.4% w/v 2ml PFS, 3mlPFS	
Sodium Hyaluronate Ophthalmic Solution 1% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Solution 1% w/v 2ml PFS	Class IIb
Sodium Hyaluronate Ophthalmic Solution 1.2% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Ophthalmic Solution 1.4% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Ophthalmic Solution 1.6% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Ophthalmic Solution 1.8% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Ophthalmic Solution 2.4% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	
Sodium Hyaluronate Ophthalmic Solution 3% w/v 1ml PFS, 1.5ml PFS, 1.6ml PFS	

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	543378 MR2
Certificate unique ID	170748221
Effective date	2020-10-06
Expiry date	2024-05-26
Frankfurt am Main	2020-10-06

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

HEIL PHARMA
Be Healthy And Happy

EU DECLARATION OF CONFORMITY

Product Identification: **iOcuVida 1%**

Batch No.: HXXXXXXX **Exp. Date:** YYYY/MM

GMDN No.: 35907

Product Description

Sodium Hyaluronate Ophthalmic Solution 1 %

iOcu Vida 1% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.

Manufacturer:

Heil Pharma

Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA

Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA

Authorized Representative

MED DEVICES LIFESCIENCES B.V.,

Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.

Standards Applied

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

We hereby confirm that the product fulfils the requirements for a CE-mark (a medical device of Class IIb) according to Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC, Article 12 for Procedure Pack. iOcu Vida 1% is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: 1) Anterior Segment Surgery 2) IOL Implantation and Cataract Surgery.

- The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 (Module H) of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

1. Mutual compatibility of the device is carried out according to the manufacturer instruction.
2. Procedure pack is packed according to manufacturer instruction.
3. The whole activity is subjected to appropriate methods of inspection.

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

Manager- Quality Assurance

Date:

EU DECLARATION OF CONFORMITY
Product Identification: **iOcuVida 1.2%** **Batch No.:** HXXXXXXX **Exp. Date:** YYYY/MM **GMDN No.:** 35907
Product Description **Sodium Hyaluronate Ophthalmic Solution 1.2 %** iOcu Vida 1.2% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.
Manufacturer: **Heil Pharma** Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA
Authorized Representative MED DEVICES LIFESCIENCES B.V., Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.
Standards Applied EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

We hereby confirm that the product fulfils the requirements for a CE-mark (a medical device of Class IIb) according to Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC, Article 12 for Procedure Pack. iOcu Vida 1.2% is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: 1) Anterior Segment Surgery 2) IOL Implantation and Cataract Surgery.

- The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 (Module H) of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

HEIL PHARMA INDIA AHMEDABAD GUJARAT

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

1. Mutual compatibility of the device is carried out according to the manufacturer instruction.
2. Procedure pack is packed according to manufacturer instruction.
3. The whole activity is subjected to appropriate methods of inspection.

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

Manager- Quality Assurance

Date:

HEIL PHARMA
Be Healthy And Happy

EU DECLARATION OF CONFORMITY

Product Identification: **iOcuVida 1.4%**

Batch No.: HXXXXXXX **Exp. Date:** YYYY/MM

GMDN No.: 35907

Product Description

Sodium Hyaluronate Ophthalmic Solution 1.4 %

iOcu Vida 1.4% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.

Manufacturer:

Heil Pharma

Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA

Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA

Authorized Representative

MED DEVICES LIFESCIENCES B.V.,

Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.

Standards Applied

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

We hereby confirm that the product fulfils the requirements for a CE-mark (a medical device of Class IIb) according to Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC, Article 12 for Procedure Pack. iOcu Vida 1.4% is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: 1) Anterior Segment Surgery 2) IOL Implantation and Cataract Surgery.

- The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 (Module H) of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

HEIL PHARMA INDIA AHMEDABAD GUJARAT

HEIL PHARMA

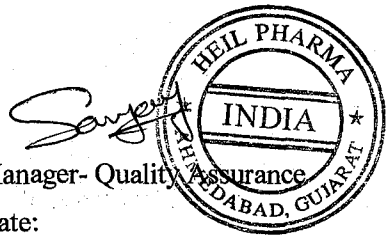
Mfg. Unit : A-114, Shayona Center, Next to Shayona Estate Memco, Naroda, Ahmedabad-38 025, Gujarat, India

M : 9998367371 Email : info@heilpharma.com, export@heilpharma.com Website : www.heilpharma.com

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

1. Mutual compatibility of the device is carried out according to the manufacturer instruction.
2. Procedure pack is packed according to manufacturer instruction.
3. The whole activity is subjected to appropriate methods of inspection.



Manager- Quality Assurance

Date:

HEIL PHARMA
Be Healthy And Happy

EU DECLARATION OF CONFORMITY
Product Identification: **iOcuVida 1.6%** **Batch No.:** HXXXXXXX **Exp. Date:** YYYY/MM **GMDN No.:** 35907
Product Description **Sodium Hyaluronate Ophthalmic Solution 1.6 %** iOcu Vida 1.6% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.
Manufacturer: **Heil Pharma** Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA
Authorized Representative MED DEVICES LIFESCIENCES B.V., Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.
Standards Applied EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

We hereby confirm that the product fulfils the requirements for a CE-mark (a medical device of Class IIb) according to Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC, Article 12 for Procedure Pack. iOcu Vida 1.6% is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: 1) Anterior Segment Surgery 2) IOL Implantation and Cataract Surgery.

- The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 (Module H) of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

HEIL PHARMA INDIA

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

1. Mutual compatibility of the device is carried out according to the manufacturer instruction.
2. Procedure pack is packed according to manufacturer instruction.
3. The whole activity is subjected to appropriate methods of inspection.

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

Manager- Quality Assurance

Date:

HEIL PHARMA
Be Healthy And Happy

EU DECLARATION OF CONFORMITY

Product Identification: **iOcuVida 1.8%**

Batch No.: HXXXXXXX **Exp. Date:** YYYY/MM

GMDN No.: 35907

Product Description

Sodium Hyaluronate Ophthalmic Solution 1.8 %

iOcu Vida 1.8% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.

Manufacturer:

Heil Pharma

Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA

Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA

Authorized Representative

MED DEVICES LIFESCIENCES B.V.,

Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.

Standards Applied

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

We hereby confirm that the product fulfils the requirements for a CE-mark (a medical device of Class IIb) according to Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC, Article 12 for Procedure Pack. iOcu Vida 1.6% is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: 1) Anterior Segment Surgery 2) IOL Implantation and Cataract Surgery.

- The product is in conformance with requirements according to the essential safety requirements as per Annex I and Route of conformity assessment as per Annex II excluding section 4 (Module H) of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

HEIL PHARMA INDIA AHMEDABAD GUJARAT

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

1. Mutual compatibility of the device is carried out according to the manufacturer instruction.
2. Procedure pack is packed according to manufacturer instruction.
3. The whole activity is subjected to appropriate methods of inspection.

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

Manager- Quality Assurance
Date:

EU DECLARATION OF CONFORMITY

Product Identification: **iOcuVida 2.4%**

Batch No.: HXXXXXXX **Exp. Date:** YYYY/MM

GMDN No.: 35907

Product Description

Sodium Hyaluronate Ophthalmic Solution 2.4 %

iOcu Vida 2.4% is a sterile, non-pyrogenic, viscoelastic preparation of highly purified high molecular weight Sodium Hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.

Manufacturer:

Heil Pharma

Reg. office: FF/114, Shayona Centre, Nr. Memco Cross Road, Memco, Ahmedabad, Gujarat, INDIA

Manufacturing Unit at: Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chhatral, Gandhinagar, Gujarat, INDIA

Authorized Representative

MED DEVICES LIFESCIENCES B.V.,

Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.

Standards Applied

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009, EN 1041:2008, EN ISO 10993-1:2009/AC: 2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, ISO/CD TS 22421.2, ISO 2859-1:1999, EN ISO 11737-1: 2006/AC:2009, EN ISO 11737-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 14155:2011/AC:2011, IEC 62366-1:2015 /COR 1:2016, IEC/TR 62366-2:2016, EN ISO 14630:2009, EN ISO 15798:2010, ISO 14698-1:2003, ISO 14698-2:2003/COR 1:2004, ISO 14644-1:2015, ISO 14644-2:2015

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HEIL PHARMA INDIA AHMEDABAD, GUJARAT

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- CE certification No. 543378MR2 Validity date: 26/05/2024.
- This declaration is on the sole responsibility of the manufacturer.

Procedure Pack:

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HEIL PHARMA INDIA AHMEDABAD, GUJARAT

Manager- Quality Assurance

Date: