HEIL PHARMA
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EC Declaration of Conformity

Product Identification: **Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2% w/v & 2.4% w/v**

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

GMDN No.: 35907

Product Description

Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2% w/v & 2.4% w/v (iVista Vida)

iVista Vida is a is a sterile non-pyrogenic, viscoelastic preparation of a non-inflammatory, highly purified grade Hydroxypropyl methylcellulose dissolved in a physiological buffer at pH 6.8-7.6. It is a clear solution supplied in a disposable glass syringe in 2ml or 3ml fill volume.

Manufacturer:

Heil Pharma

Plot No. 450, Behind Jay Banas Metals Pvt. Ltd., Opposite- Nirma Factory Chatral , Gandhinagar, Gujarat, INDIA

Authorized Representative

MED DEVICES LIFESCIENCES B.V.,

Address : Kraijenhoffstraat 137 A, 1018RG Amsterdam, The Netherlands.

E-Mail: info@meddevices.net

Standards Applied

EN ISO 13485:2012, EN ISO 17665-1:2006, EN 556-1:2001, EN ISO 14971:2012, EN 980:2008, EN 1041:2008, EN ISO 15798:2010, EN ISO 14630:2009, ISO 15223-1:2016, ISO 2859-1:1999, 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 10993- 11: 2009, 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, EN 62366:2008, ISO 14698-1:2003, ISO 14698-2:2003, 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. iVista Vida is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including: Anterior Segment Surgery, Cataract Surgery Implantation, Corneal Transplantation & Glaucoma 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.
- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.

Digitally signed by Rusu Ghenadie
Date: 2021.10.08 14:06:33 EEST
Reason: MoldSign Signature
Location: Moldova

HEIL PHARMA INDIA AHMEDABAD, GUJARAT

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- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE Registration No:543378 MR2 CE Certificate Unique ID:170748221 Validity date: 2024/05/26.
- 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: 27/01/2021

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EC Declaration of Conformity

Product Identification: Sodium Hyaluronate Ophthalmic Solution 1.0% w/v, 1.2% w/v, 1.4% w/v, 1.6% w/v, 1.8% w/v, 2.4% w/v, 3.0% w/v

Batch No.: HXXXXX **Exp. Date:** XXXX/XX

GMDN No.: 35907

Product Description

Sodium Hyaluronate Ophthalmic Solution 1.0% w/v, 1.2% w/v, 1.4% w/v, 1.6% w/v, 1.8% w/v, 2.4% w/v, 3.0% w/v (iOcuVida)

iOcuVida 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 in 1ml & 1.6ml

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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We hereby confirm that the product fulfills 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. Sodium Hyaluronate Ophthalmic Solution 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.
- The product is manufactured according to Good Manufacturing Practices.
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- Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str.2160433, Frankfurt am main having Notified Body Number (0297).
- CE Registration No:543378 MR2 CE Certificate Unique ID:170748221 Validity date:2024/05/26.
- 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: 02/04/2021