

| DECLARATION OF CONFORMITY | |
|--|---|
| Product Identification SODIUM HYALURONATE SOLUTION (10 mg/ml) | |
| Brand: BIOVISC ORTHO | Presentation: 2ml PFS GMDN Code: 44757 |
| Product Description Sodium Hyaluronate Solution 10 mg/ml for Osteoarthritis Use | |
| Batch No. XXXX | Exp Date. YYYY/MM |
| Manufacturer: Bio-Tech Vision Care Pvt. Ltd. Plot No.4, PHARMEZ, Sarkhej-Bavla N.H 8A, Village: Matoda, Taluka: Sanand, Dist. Ahmedabad-382 213, Gujarat, India. | |
| Authorized Representative Biotech Europe Meditech Inc Limited, AF2, IDA Business & Technology Park, Roscommon, Ireland | |
| Standards Applied EN ISO 13485:2016+A11:2021, EN ISO 17665-1:2006, EN 556-1:2001+AC:2006, EN ISO 14971:2019+A11:2021, ISO 20417:2021, ISO 14630:2012, EN ISO 15223-1:2021, ISO 2859-1:1999+Amd1:2011, ISO 10993-1:2018, EN ISO 10993-3:2014, EN ISO 10993-5:2009, ISO 10993-6:2016, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, ISO 10993-18:2020+AMD1:2022, ISO/TS 10993-19:2020, EN ISO 11737- 1:2018+A1:2021, EN ISO 11737-2:2020, ISO 11607-1:2019+Amd 1:2023, ISO 11607-2:2019+Amd 1:2023, ISO 14155:2020, IEC 62366-1:2015+AMD 1:2020, ISO 2247:2000, ISO 14698-1:2003, ISO 14698- 2:2003+Cor1:2004, ISO 14644-1:2015, ISO 14644-2:2015, Ph.Eur.,British Pharmacopoeia | |

- We hereby confirm that the product fulfills the requirements for a CE-mark for Class III Medical Device according to Rule 8, Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC.
- 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 of the Council Directive 93/42/EEC, as amended by 2007/47/EC.

BIOTECH VISION CARE PVT. LTD.

Manufacturing Unit 1:

Plot No. 555-556-557,
Opp. Subham Tex-O-Pack,
Khatraj-Vadsar Road,
P.O.: Khatraj, Taluka, Kalol,
Dist. Gandhinagar,
Gujarat, India

+ 91 - 02764-662000

Manufacturing Unit 2:

Plot No. 4,
PHARMEZ, Sarkhej-Bavla N.H.
8A, Village: Matoda,
Taluka: Sanand, Dist.:
Ahmedabad- 382213,
Gujarat, India

+ 91 - 02717-681800

Manufacturing Unit 3:

First floor,
Plot no. 555, 556, 557 Khatraj-
Vadsar Road, Opp. Shubham
Tex-O-Pack, Village Khatraj, Taluka
Kalol, Dist. Gandhinagar,
Gujarat, India

+ 91 - 02764-662000

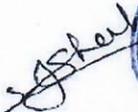
CORPORATE OFFICE

Block 1,
Abhishree Corporate Park,
Opp. Swagat Bunglow, BRTS Stop
Bopal - Ambli Road,
Ahmedabad - 380 058
Gujarat, India.

+ 91 - 79 - 66823000

- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DNV Product Assurance AS (Id: 2460), Address: Veritasveien 1, 1363 Høvik, Norway.
- CE certification No: 282516-2019-CE-IND-NA-PS Rev. 1.0 Validity Extension date: 31 December 2027.
- This declaration is on the sole responsibility of the manufacturer.

Signature:


Name : Suyog Shah

Title : AGM - Quality Assurance

Place & Date : Ahmedabad & March 20th, 2024

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