

DECLARATION OF CONFORMITY	
Product Identification	
CROSSLINKED SODIUM HYALURONATE SOLUTION (30 mg/ml)	
Brand: Biovisc Ortho Single	Presentation: 3ml PFS GMDN Code: 44757
Product Description	
Crosslinked Sodium Hyaluronate Solution 30 mg/ml for Osteoarthritis Use	
Batch No. XXXX	Exp. Date: YYYY/MM
Manufacturer:	
BioTech 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	
Neuvida Medical Device Inc Limited, 136-137 Churchill House, Stirling Way, Borehamwood, WD6 2HP, England	
Standards Applied	
EN ISO 13485:2016/AC:2016, EN ISO 17665-1:2006, EN 556-1:2001/AC:2006, EN ISO 14971:2012, EN 1041:2008, EN ISO 14630:2009, EN ISO 15223-1:2016, ISO 2859-1:1999/Amd1:2011, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, 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/ AC:2011, EN 62366:2008, ISO 14698-1:2003, ISO 14698-2:2003/Cor1:2004, ISO 14644-1:2015, ISO 14644-2:2015	

- We hereby confirm that the product fulfils 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.
- The product is manufactured according to Good Manufacturing Practices.
- The manufacturer is responsible for quality control of the product.
- Notified Body: DNV GL Presafe AS (Id: 2460), Address: Veritasveien 3, N-1363 Høvik, Norway
- CE certification No. 282516-2019-CE-IND-NA-PS Rev. 0.0 Validity date: 19 November 2023
- This declaration is on the sole responsibility of the manufacturer.

Signature:

Name: **Suyog Shah**
 Title: **Sr. Manager (Quality Assurance)**
 Date: **February 18, 2019**



CORPORATE OFFICE

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