biotech

DECLARATION OF CONFORMITY		
Product Identification **SODIUM HYALURONATE SOLUTION (20 mg/ml)** Brand: **Biovisc Ortho Plus**	Presentation: **2ml PFS**	GMDN Code: **44757**
Product Description **Sodium Hyaluronate Solution 20 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 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.
- 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:

BIOTECH VISION CARE PVT. LTD. AHMEDABAD

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