



# DET NORSKE VERITAS

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

Certificate No. 74818-2010-CE-IND-NA Rev. 1.0

This Certificate consists of 4 pages

*This is to certify that the Quality Management System of*

**BioTech Ophthalmics Pvt. Ltd.**

India

*for production and final product inspection/testing of*

**Solutions for Ophthalmic, Osteoarthritis and Urology Use**

*has been assessed with respect to*

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*

Høvik, 26 October 2010

*This Certificate is valid until:*

**12 January 2015**

For DET NORSKE VERITAS CERTIFICATION AS  
NORWAY



Aud Løken Eiklid  
*Certification Manager*

Notified Body No.:  
0434

Jenny Helen Nytnun  
*Technical Reviewer*

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info.*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

## Certificate history

Revision	Description	Issue Date
	Original certificate no. 2005-OSL-MDD-0012	2005-01-12
	Recertification	2010-01-12
<b>1.0</b>	<b>Addition of new products (in bold)</b>	<b>2010-10-26</b>

## Products covered by this Certificate

Product Description	Product Name	Class
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution USP 2% w/v, <b>2.4% w/v and 3.0% w/v</b>	Eye Visc <ul style="list-style-type: none"> <li>▪ 3 ml and 5 ml vial</li> <li>▪ Eye Visc PFS 2 ml, <b>2.5 ml and 3ml</b></li> <li>▪ <b>I-Visc PFS 2 ml, 2.5 ml and 3ml</b></li> <li>▪ Eye Visc plus PFS 2ml, <b>2.5 ml and 3ml</b></li> <li>▪ <b>Eye Visc PFS 2.4% (2ml, 2.5 ml &amp; 3 ml PFS)</b></li> <li>▪ <b>Eye Visc PFS 3.0% (2ml, 2.5 ml &amp; 3 ml PFS)</b></li> </ul> Metilon (3ml vial, 5ml vial) <b>Metilon 20 PFS 2ml, 3 ml</b> <b>Metilon Plus PFS 2 ml</b> <b>Metilon 24 PFS 2 ml</b> Techno Instruments Visc (3ml vial, 5ml vial, PFS 2ml)	I Ib
Trypan blue (0.06% w/v) Ophthalmic solution	Bio-Blue <ul style="list-style-type: none"> <li>▪ 1 ml vial and <b>Pack of 5 or 10 vials</b></li> <li>▪ 1 ml PFS and <b>Pack of 5 or 10 PFS</b></li> </ul>	I Ib
Trypan Blue(0.15% w/v) ophthalmic solution	Bio-Blue Plus <ul style="list-style-type: none"> <li>▪ 1 ml vial and <b>Pack of 5 or 10 vials</b></li> <li>▪ 1 ml PFS and <b>Pack of 5 or 10 PFS</b></li> </ul>	I Ib
Brilliant Blue G or Acid Blue 90 (0.25 mg/ml)	Bio Blue 90 <ul style="list-style-type: none"> <li>▪ 0.5 ml and 1 ml vial and <b>Pack of 5 or 10 vials</b></li> <li>▪ 0.5 ml and 1 ml PFS</li> </ul>	I Ib
Sodium Hyaluronate Ophthalmic Solution	Bio-Hyalur PLUS (14 mg/ml), <ul style="list-style-type: none"> <li>▪ 0.55 ml</li> <li>▪ 0.85 ml</li> <li>▪ 1.0 ml</li> </ul> Bio-Hyalur (10 mg/ml),	I Ib



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	<ul style="list-style-type: none"> <li>▪ 0.55 ml</li> <li>▪ 0.85 ml</li> <li>▪ 1.0 ml</li> </ul> Bio-Hyalur DUO <ul style="list-style-type: none"> <li>▪ 0.55 ml</li> <li>▪ 0.85 ml</li> <li>▪ 1.0 ml</li> </ul> Bio-Hyalur MV (16 mg/ml) Bio-Hyalur EV (18 mg/ml) Bio-Hyalur HV (24mg/ml) Bio-Hyalur 1.2% <b>Bio Hyalur SV (30mg/ml)</b> <ul style="list-style-type: none"> <li>▪ 0.5 ml</li> <li>▪ 0.8 ml</li> <li>▪ 1.0 ml</li> </ul> Bio-Vial <ul style="list-style-type: none"> <li>▪ 2.0 ml</li> </ul>	
Silicone Oil 1000cst	BIOSIL 10 ml vial and PFS TECHNO INSTRUMENTS 10ml vial and PFS	IIb
Silicone Oil 5000cst	BIOSIL-F 10 ml vial and PFS TECHNO INSTRUMENTS 10ml vial and PFS	IIb
<b>Heavy Silicone Oil 1400 mPas</b>	<b>BIOSIL HV 10 ml vial and PFS</b>	<b>IIb</b>
<b>Heavy Silicone Oil 300 mPas</b>	<b>BIOSIL LV 10 ml vial and PFS</b>	<b>IIb</b>
<b>Perfluoro-n-octane liquid</b>	<b>BIO OCTANE 5 and 7 ml vial and PFS</b>	<b>IIb</b>
<b>Perfluorodecalin liquid</b>	<b>BIO DECALIN 5 and 7 ml vial and PFS</b>	<b>IIb</b>
<b>Perfluoro-n-octane and Perfluorohexyloctane liquid</b>	<b>BIO OCTANE PLUS 5 and 7 ml vial and PFS</b>	<b>IIb</b>
<b>Perfluorodecalin and Perfluorohexyloctane liquid</b>	<b>BIO DECALIN PLUS 5 and 7 ml vial and PFS</b>	<b>IIb</b>
<b>Vitreous Substitute-Perfluorohexyloctane liquid</b>	<b>BIO VITREOUS 6 ml and 9 ml vial</b>	<b>IIb</b>
Sodium Hyaluronate Solution for Osteoarthritis Use	Bio Visc Ortho <ul style="list-style-type: none"> <li>▪ 1 ml</li> <li>▪ 2 ml</li> <li>▪ 3 ml</li> </ul>	IIb
<b>Sodium Hyaluronate Solution 40 mg/50 ml for Urology use</b>	<b>Bio Cyst 50 ml vial</b>	<b>IIb</b>

The complete list of devices is filed with the Notified Body.



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## Sites covered by this certificate

Site Name	Address
BioTech Ophthalmics Pvt. Ltd.	Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-o-pack, Khatraj, Tk. Kalol, Dist. Gandhinagar, Gujarat, India

## EU Representative

Mr. Siddharth Asnani, 17 Wellesley Road, IIFord, Essex IG1 4JT, United Kingdom

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE