



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 59698-2009-CE-IND-NA

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

BioTech Ophthalmics Pvt. Ltd.

India

for production and final product inspection/testing of

Hyaluronic Acid Gel for Dermal use

has been assessed with respect to

the conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 17 August 2009

This Certificate is valid until:

17 August 2014

For DET NORSKE VERITAS CERTIFICATION AS
Norway



Notified Body No.:
0434


Spæren, Marianne
Certification Manager


Aud Løken Eiklid
Technical Reviewer

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.



Cert. No.: 59698-2009-CE-IND-NA
Rev. No.: 0.0
Project No.: PRJC-14185-2007-PRC-IND

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
0	Original certificate	2009-08-17

Products covered by this Certificate

Product Description	Product Name	Class
Non-cross linked Hyaluronic Acid Gel for Dermal use	<ul style="list-style-type: none">▪ Jeunesso 20▪ Jeunesso 30	III
Cross-linked Hyaluronic Acid Gel for Dermal use	<ul style="list-style-type: none">▪ Jeunesso 20L▪ Jeunesso 30L	III

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

Sites covered by this certificate

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

EU Representative

Mr. Anil Gupta, Aves Opticians, 14 The Broadway , Rainham , Essex RM 13 9YW, United Kingdom



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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

EC design-examination certificate

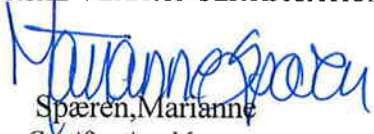

Medical Devices



Design Approval no. 59698-2009-CE-IND

Manufacturer name: BioTech Ophthalmics Pvt. Ltd.	
Manufacturer address: First Floor 555 / 556 / 557, Khatraj-Vadsar Road, Opp. Shubham Texopack, VIII Khatraj, TK. Kalol, District Gandhinagar, Gujarat India	
Type of medical device and identification no.: Cross-linked and non-cross linked Hyaluronic Acid Gel for Dermal use: <ul style="list-style-type: none"> ▪ Jeunesse 20 ▪ Jeunesse 20L ▪ Jeunesse 30 ▪ Jeunesse 30L 	Class of Medical Device: III
Short description of the medical device: Jeunesse (all type) is an injectable gel, sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colourless, homogenized gel implant for dermal use. It consists of crosslinked or non-crosslinked Hyaluronic Acid formulated to a concentration of 20 mg/ml and 30 mg / ml suspended in a physiological buffer. No animal protein is contained in Jeunesse. HA is naturally occurring polysaccharide of extracellular matrix in human tissues including skin. The hyaluronic Acid polymers are essential for the metabolism of skin and vital to its hydration. Mainly with aging process, human skin loses its essential extracellular matrix components like HA. It is available in four different concentrations: Jeunesse 20(20 mg/ml) and Jeunesse 30 (30 mg/ml) contains non cross linked Hyaluronic acid. Jeunesse 20 L (20 mg/ml) and Jeunesse 30 L (30 mg/ml) contains cross linked Hyaluronic Acid. They are supplied in 1 ml BD glass syringe delivering 0.5, 0.8 and 1 ml of gel.	
<p>This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.</p> <p>Limitations:</p> <p>Any changes in the Design shall immediately be reported to Det Norske Veritas Certification AS in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.</p>	

This certificate is valid until: 17 August 2014

for DET NORSKE VERITAS CERTIFICATION AS  Spæren, Marianne Certification Manager	Høvik, 17 August 2009  for Aud Løken Eiklid Technical Reviewer
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This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.