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# DNV BUSINESS ASSURANCE

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## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

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Certificate No. 74818-2010-CE-IND-NA Rev. 5.0  
This Certificate consists of 4 pages

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

### **BioTech Ophthalmics Pvt. Ltd.**

Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Subham Tex-O-Pack, Village Khatraj, Tal. Kalol, Dist.  
Gandhinagar, Gujarat, India

*for design, production and final product inspection/testing of*

### **Solutions for Ophthalmic 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, 13 April 2015

*This Certificate is valid until:*

**12 April 2020**

For DNV GL BUSINESS ASSURANCE  
NORWAY AS



Aud Løken Eiklid  
Certification Manager

Notified Body No.:  
0434

Angela Lanna  
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.